Supreme Court, U.S.
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No. 02-

IN THE
Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M. J. MADEY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether non-profit universities are precluded from asserting the experimental use exemption from liability for patent infringement merely because their research programs serve legitimate educational purposes.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit (App. A, *infra*, 1a to 30a), is reported at 307 F.3d 1351. Neither of the district court opinions (App. B & C, *infra*, 31a to 99a) is reported.

STATEMENT OF JURISDICTION

The United States Court of Appeals for the Federal Circuit entered its judgment on October 3, 2002. This Court has jurisdiction over this petition pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the proper interpretation of 35 U.S.C. § 271(a), which provides:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States during the term of the patent therefor, infringes the patent.

The statute was enacted pursuant to Article I, Section 8, Clause 8 of the United States Constitution, which provides:

> The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

STATEMENT OF THE CASE

John M.J. Madey ("Dr. Madey"), a scientist and scholar in the field of electromagnetic radiation, invented the free electron laser ("FEL"). (App. A, *infra*, at 2a). Dr. Madey and his colleagues developed two inventions at issue in this case: a microwave electron gun, which is used as an electron source for the FEL and is the subject of U.S. Patent No. 4,641,103 ("the '103 patent"); and a "phase-locking" process and apparatus known as the "Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution and Fast Time Resolution Spectroscopy," which is the subject of U.S. Patent No. 5,130,994 ("the '994 patent"). (App. A, *infra*, at 3a-4a).

After conducting research at Stanford University, Dr. Madey left Stanford for Duke University ("Duke" or "the University") in 1989. (App. A, *infra*, at 2a). Duke built an FEL research lab to house FEL equipment, including the Mark III FEL, which had been transferred by the government and Stanford to Duke. (App. A, *infra*, at 2a). Dr. Madey served as director of the Duke FEL Lab for almost a decade. (App. A, *infra*, at 3a). Determining that Dr. Madey was not a competent manager, Duke removed him as director of the FEL Lab in 1997. Dr. Madey subsequently resigned from the University. (App. A, *infra*, at 3a).

After his removal as director, Dr. Madey sued Duke, alleging violations of the Age Discrimination in Employment Act of 1967 and the federal patent law, 35 U.S.C. § 271(a), in addition to various common-law claims. Dr. Madey invoked the district court's jurisdiction under 28 U.S.C. §§ 1331 and 1338(a), and alleged that Duke's use of two microwave electron guns in the Duke FEL Lab violated the '103 patent. (App. A, *infra*, at 3a). Approximately nine

months later, Dr. Madey filed an amended complaint, adding, among other things, an additional claim that Duke's use of the Mark III FEL in the Duke FEL Lab infringed the '994 patent. Madey also amended his original patent infringement claim to allege that Duke infringed the '103 patent through its use of a so-called Test Stand Gun.

Duke moved to dismiss the '103 patent claim with regard to the two guns in the Duke FEL Lab, arguing that the Court of Claims had exclusive subject matter jurisdiction over this claim. The district court granted the motion to the extent Duke's uses of the '103 patent were undertaken pursuant to a federal grant, ruling that the uses were essentially "by and for" the government within the meaning of 28 U.S.C. § 1498(a). (App. C, *infra*, at 66a-70a). The district court retained jurisdiction over the infringement claim to the extent it alleged use of the patent outside the scope of the federal grant. (App. C, *infra*, at 70a).

After substantial discovery, Duke moved for partial summary judgment on Dr. Madey's remaining patent infringement claims. (App. B, *infra*, at 31a-32a). Duke contended that it could not be held liable for any potential infringement of the '103 and '994 patents because "essentially all" of its research "was authorized by the Government, conducted for the Government, or funded by the Government." (App. B, *infra*, at 39a). Duke also argued that uses of the '103 and '994 patents were excepted from Section 271(a) liability pursuant to the "experimental use exception" because they were undertaken in pursuit of academic research with no commercial purpose. (App. B, *infra*, at 39a).[1]

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1. Duke filed a separate motion for partial summary judgment of non-infringement of the '103 patent with respect to the Test Stand (Cont'd)

The district court granted Duke's motion for partial summary judgment based on the experimental use exception and declined to exercise supplemental jurisdiction over the remaining state law claims. (App. B, *infra*, at 53a-54a).[2] The court determined that, "[a]lthough the scope of the defense has recently been the issue of much debate, to date, the experimental use defense remains viable and may be asserted in those cases in which the allegedly infringing use of the patent is made for experimental, non-profit purposes only." (App. B, *infra*, at 40a (citations omitted)). The district court concluded that the record supported Duke's contention that its "primary purpose is to teach, research, and expand knowledge, and not to engage in patent development for the purpose of commercial benefit." (App. B, *infra*, at 43a). The district court also concluded that "all of [Duke's] uses of the devices covered by the '103 and '994 Patents have been in furtherance of its educational purpose or for experimentation only." (App. B, *infra*, 44a, citations omitted). Accordingly, the district court held that the evidence could not support a jury verdict in Dr. Madey's favor. (App. B, *infra*, at 46a).

Dr. Madey appealed the district court's judgment, (App. A, *infra*, at 1a), and the United States Court of Appeals for the Federal Circuit reversed. The Federal Circuit first held that the district court erred in deciding that any uses of the patented FEL equipment falling within Duke's federal

(Cont'd)

Gun. The district court granted Duke's summary judgment motion, and the Federal Circuit affirmed this decision on appeal. (App. A, *infra*, at 27a-28a).

2. Dr. Madey's other claims arising under federal law had previously been dismissed pursuant to Fed. R. Civ. P. 12(b)(6). (App. C, *infra*, at 99a).

grant should be dismissed as uses "by and for the government." (App. A, *infra*, at 189). The court concluded that the district court failed to "clearly identify, discuss or analyze the particular statements or aspects of the [federal] grant that may have provided the government's authorization or consent to be sued[,]" (App. A, *infra*, at 18a), and remanded this aspect of the case to the district court to determine "which uses fall within the scope of the [federal] grant and which uses are outside that scope." (App. A, *infra*, at 20a).

The Federal Circuit also reversed the district court's decision granting summary judgment on Dr. Madey's patent infringement claims based on the experimental use exception. The Federal Circuit acknowledged that its precedent established that the user of a patented invention is not liable for infringement if the use is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." (App. A, *infra*, at 26a). The court of appeals, however, viewed this "experimental use defense" as "very narrow and strictly limited" such that the 'slightest commercial implication'" destroys it. (App. A, *infra*, at 24a). The Federal Circuit then went further. It concluded that research institutions or entities engaging in wholly non-commercial endeavors were liable for patent infringement if their uses of patented inventions furthered their "legitimate business." (App. A, *infra*, at 26a). Since an academic research institution's "business" is experimentation, the Federal Circuit's formulation of the exception renders it an empty shell, unavailable to the very entities the exemption was intended to cover.

The Federal Circuit wrongly relied on *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976), which merely held, consistent with the explicit language of 28 U.S.C. § 1498, that a plaintiff has a remedy in the Court of Claims against

the United States for the infringing manufacture of goods for the United States if the goods were not manufactured for experimental purposes, even if the United States ultimately uses the goods for experimental purposes. *See* 547 F.2d at 1125-26. Misapplying language from *Pitcairn*, the court of appeals held that no "alleged infringer" of a patent may take advantage of the experimental use doctrine if its non-commercial use of a patented invention in any way furthers the "infringer's legitimate business." (App. A, *infra*, at 25a).

In reaching this conclusion, the Federal Circuit disapproved of *Ruth v. Stearns-Roger Mfg. Co.*, 12 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936), the only reported case addressing application of the experimental use exception to an academic institution's non-commercial use of a patented invention. (App. A, *infra*, at 25a). In *Ruth*, the district court held that "a manufacturer of equipment covered by patents was not liable for contributory infringement because the end-user purchaser was the Colorado School of Mines, which used the equipment in furtherance of its educational purpose." (App. A, *infra*, at 25a). The Federal Circuit concluded that *Ruth* was "inconsistent" with Federal Circuit precedent. (App. A, *infra*, at 25a).

In light of its legal conclusions, the Federal Circuit remanded the case to the district court to determine if Duke's use of the patented inventions furthered Duke's "legitimate business objectives, including educating and enlightening students and faculty" or "increas[ing] the status of the institution and lur[ing] lucrative research grants." (App. A, *infra*, at 25a).

REASONS FOR GRANTING THE PETITION

Supreme Court review is necessary because the Federal Circuit's decision, which effectively is the law of the land, disrupts a delicate balance in the patent law, contrary to the legislative judgment of Congress and the "settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1841 (2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)). The centuries-old experimental use exception to patent infringement diffuses the inherent tension between encouraging invention through limited monopoly and furthering innovation and science by providing the public with access to knowledge.

Congress implicitly embraced the exception when recodifying the patent laws in 1952. The Federal Circuit Court's decision, however, overrules Congress' legislative judgment and creates an untenable paradox: non-profit research institutions are now precluded from making experimental use of patents to further knowledge and research while avowedly commercial enterprises may still take advantage of the exception.

The Federal Circuit's decision has monumental consequences for scientific research in this country. Much scientific research involves a multitude of patents or a single patent that is the keystone to all further research in a particular area. Until now, scientists at non-profit universities and research institutions have assumed that their research does not implicate patent law so long as it serves no immediate commercial purpose. This assumption has allowed critical non-profit research in fields such as molecular biology and biotechnology to move forward without the prohibitive

costs, substantial delays, or complete roadblocks that might otherwise be associated with multiple patents, exclusive licensing rights, or an uncooperative patent holder. The Federal Circuit's decision brings the science community's long-standing course of conduct into serious question and jeopardizes the framework under which much non-profit research is conducted. By explicitly eliminating the experimental use exception for research institutions, the Federal Circuit's opinion undoubtedly will have a significant chilling effect on research at major universities and other non-profit research institutions.

I.

THE FEDERAL CIRCUIT'S DECISION, WHICH NOW STANDS AS THE LAW OF THE LAND, UNCAUTIOUSLY DISRUPTS BOTH THE DELICATE PATENT LAW BALANCE EMBRACED BY CONGRESS AND THE SETTLED EXPECTATIONS OF THE INVENTING COMMUNITY

The United States Constitution allows Congress to grant inventors exclusive rights to their inventions for a limited time in order to "promote the Progress of Science." U.S. Const. art. I, § 9, cl. 8. Such exclusive rights may motivate invention but also may act as a barrier to future inventions. *See* Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AIPLA Q. J. 52, 53 (1993). Consequently, "[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself. . . ." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

The experimental use exception, which has been in existence since the early nineteenth century, forms part of this balance. Justice Story first alluded to the exception in 1813 while sitting on the Massachusetts Circuit Court in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). In *Whittemore*, the defendant challenged a jury instruction that "the making of a machine fit for use, and with a design to use it for profit, was an infringement of the [plaintiff's] patent right." 29 F. Cas. at 1121. Justice Story upheld the instruction in its entirety, noting that it was "certainly favorable to the defendant." *Id.* Justice Story observed that "it could never have been the intention of the legislature to punish a man, who constructed . . . a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Id.*

Justice Story gave more explicit content to the "experimental use exception" in *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391). In holding that a sheriff could not be liable for patent infringement for seizing and selling materials forming a patented machine, Justice Story noted that "the making of a patented machine to be an offence within the purview of [the patent laws] must be the making ***with an intent to use for profit***, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification." 21 F. Cas. at 555 (emphasis added).

By the end of the century, the experimental use exception was well entrenched in the common law. In *Poppenhusen v. Falke*, 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11,279), for example, the court considered it "well settled" that "an experiment with a patented article for the sole purpose

of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee." 19 F. Cas. at 1049. And, in 1890, the experimental use exception was summarized in a leading treatise, *The Law of Patents for Useful Inventions*, by William C. Robinson. Robinson's treatise explicitly recognized that the use of a patent that "produce[d] no pecuniary result" was not a violation of the patent laws:

> § 898. No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented Invention.
>
> Moreover, the interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized,

> the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. . . .

3 William C. Robinson, *The Law of Patents for Useful Inventions* 55-56 (photo. reprint 1972) (1890) (footnote omitted).

By the middle of the twentieth century, courts had fully accepted the dichotomy between commercial and non-commercial uses of a patent, consistently holding that experimental use of a patent for non-commercial purposes did not constitute infringement under the patent laws. *See, e.g., Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944) (excepting from patent infringement those devices manufactured by the defendant which were neither manufactured for sale nor sold but were "built . . . only experimentally"), *aff'd*, 156 F.2d 29 (2d Cir. 1946); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D.W. Va. 1937) (citations omitted) (holding that experimental testing of plaintiff's patented device before using a different variation of the device in defendant's machine "was not in law an act of infringement as [the patented device] was not commercially sold"); *Ordinance Eng'g Corp. v. United States*, 84 Ct. Cl. 1, 2, 4 (1936) (sustaining plaintiff's infringement claims against the government for manufacturing patented service shells but excepting from plaintiff's claim any ballistic or experimental shells manufactured by the government for testing and experimental use only); *cf. United States Mitis Co. v. Carnegie Steel Co.*, 89 F. 343, 351 (C.C.W.D. Pa. 1898) (defendant could not invoke the experimental use defense where the use of plaintiff's patent was "in the course of business and for profit"), *aff'd*, 90 F. 829 (3d Cir. 1898);

Bonsack Mach. Co. v. Underwood, 73 F. 206, 211 (C.C.E.D.N.C. 1896) (same). More specifically, case law established that a research institution did not infringe a patent if it used a patented invention for experimental purposes only. *See Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 703 (D. Colo. 1935) (holding that because the "sale of parts [to the Colorado School of Mines] . . . were for use in laboratory machines used for experimental purposes," the sales "did not contribute to an infringing use"), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).

This was the state of the law confronting Congress when it recodified the federal patent statute in 1952. Although Congress explicitly overruled certain judicial precedent with new statutory provisions, *see* 1 Donald S. Chisum, *Overview: Historical Development of Patent Law*, *in* Chisum on Patents OV-12 to 13 (2002), it did nothing to overrule case law on the scope of liability for the direct infringement of a patent. Congress added Section 271(a), which generally defines an infringer as one who "without authority makes, uses or sells any patented invention." 35 U.S.C. § 271(a). But Section 271(a), like most of the 1952 Patent Act, was added only as a declaration of already-established law. *See* 35 U.S.C.A. § 271, Rev. Notes and Leg. Rprts. (2001) (discussing 1952 Acts, and explaining that "[t]he first paragraph of [section 271] is declaratory only"); Chisum, *supra*, at OV-12 ("To a large extent, the 1952 Act rearranged existing statutory provisions and stated in statutory forms matters previously recognized only in court decisions and Patent Office practice . . . ."). Indeed, the Court has already acknowledged that Section 271(a) "left intact the entire body of case law on direct infringement." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 342 (1961). In enacting the 1952 Patent Act without eliminating the experimental use exception, Congress "is presumed to [have been] aware of

. . . [the] judicial interpretation of [the] statute and to [have] adopt[ed] that interpretation." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978).

In this case, the Federal Circuit overrode Congress' legislative judgment. It effectively eliminated the experimental use exception for research institutions by misapplying language from a wholly irrelevant case, *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976). *Pitcairn* stands for the unremarkable proposition that, under 28 U.S.C. § 1498, a plaintiff can recover compensation against the government in the Court of Claims for the infringing manufacture of goods for the United States where the goods are not manufactured for experimental purposes, even if the goods ultimately are used by the government for experimental purposes. *See* 547 F.2d at 1125-26. This result follows ineluctably from the disjunctive language of 28 U.S.C. § 1498(a), which provides that a plaintiff's remedy is against the United States in the Court of Claims "[w]henever an invention described in and covered by a patent of the United States is used ***or*** manufactured by or for the United States without license of the owner thereof." 28 U.S.C. § 1498(a) (emphasis added). In explaining that the products were not manufactured ***for*** experimental use, the court mentioned that testing by the government of items manufactured for it is "in keeping with the legitimate business of the using agency." *Pitcairn*, 547 F.2d at 1125-26. In other words, according to the *Pitcairn* court, the fact that the government normally tests products manufactured for it does not mean that the products are manufactured for experimental use.

Seizing on *Pitcairn's* "legitimate business" language and applying it out of context, the Federal Circuit in this case fashioned a very different rule of law: an institution may not

take advantage of the experimental use exception if its non-commercial use of a patented invention in any way furthers the "infringer's legitimate business." (App. A, *infra*, at 26a). This standard seals the coffin on the experimental use exception for private universities. No research institution will be able to demonstrate that its experimental use of any patent fails to further the institution's "legitimate business." Because such entities are "in the business" of research and education, they can never use a patent experimentally without implicating their "business" objectives, even when such objectives have absolutely no commercial elements. The Federal Circuit, moreover, has declared that a university infringes a patent when it uses a patented invention for non-commercial experimental purposes even if such use only ***indirectly*** furthers the university's interests. According to the Federal Circuit, a university's use of a patent which might arguably help to "increase [its] status" or its ability to "lure" students, faculty and grant money is a use now subject to the full proscriptive force of the patent laws. (App. A, *infra*, at 25a).

The Federal Circuit's decision thereby turns the experimental use exception on its head. To the extent the exception retains any vitality, it is available only to individuals or commercial entities not in the "business" of research or education.[3] There is no principled basis for

3. It is questionable whether the experimental use exception has any content at all after the Federal Circuit's opinion. Not only are research institutions precluded from using the defense based on the "legitimate business test," but no entity may successfully rely on the defense if its experimental use of a patent "has the slightest commercial implication." (App. A, *infra*, at 24a). Depending on the court's interpretation of "slight commercial implication," the opinion could well be the death knell for the nearly two-hundred-year-old doctrine.

subjecting non-profit research institutions to patent infringement claims for their non-commercial use of patents while allowing other private entities this safe haven. To the contrary, all policy considerations favor allowing the exception for non-profit entities seeking to advance education and knowledge.[4]

The Federal Circuit is the only court now authorized to hear patent appeals. *See* H.R. 312, 97th Cong. 20-22 (1981). Its opinions therefore create "national law precedent." *Id.* In light of this reality, the Court recently admonished the Federal Circuit to "be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 122 S. Ct. at 1841 (citation omitted). The court of appeals wholly ignored the Court's admonition in this case. Its opinion is manifestly erroneous and cannot be squared with case law as it existed in 1952 and as implicitly incorporated into the 1952 Patent Act.

The "interlocutory" nature of the Federal Circuit's decision does not counsel against review. Although the Federal Circuit remanded the case to the district court to determine if Duke's use of Dr. Madey's patents furthered its "legitimate business objectives," (App. A, *infra*, at 26a), the district court's role on remand is purely perfunctory.

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4. The Federal Circuit's opinion only broadens the inconsistencies that already exist in this area of the law. Pursuant to *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Savings Bank*, 527 U.S. 627 (1999), a public research institution whose research qualifies as "state action" may experiment with a patented invention without any liability in damages, even if the purpose of the experiment is manifestly commercial in nature. *See* 527 U.S. at 647-48. This result now stands in stark contrast to the complete abrogation of patent infringement protection for private universities.

Given the Federal Circuit's standard for deciding whether the university's use furthered its legitimate business objectives, the district court can reach only one result. In the meantime, the decision stands as the law of the land. The Court should review this case to make clear — consistent with long-settled expectations of the scientific community — that non-profit research institutions may make experimental use of patented inventions without running afoul of the patent law.

II.

THE FEDERAL CIRCUIT'S OPINION PRESENTS AN ISSUE OF GREAT NATIONAL IMPORTANCE

The Federal Circuit's opinion will have dire consequences for non-profit research institutions and for the future health of our Nation. The importance to our society of scientific research conducted at universities and other non-profit research institutions is incalculable. Many of the building blocks to this research, however, are patented. The Federal Circuit's decision threatens to delay or stymie research based on such patented inventions.

The scientific contributions of those engaged in "philosophical inquiry" cannot be exaggerated. Universities and other non-profit research institutions often seek to further knowledge and innovation — not for profit — but for the greater common good. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 Yale L.J. 177, 181-82 (1987) (hereinafter Eisenberg, *Proprietary Rights*); Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 Nw. U. L. Rev. 667, 703 (1997). In recognition of this important endeavor,

the government spends billions of dollars each year funding non-commercial research at universities. *See* Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7:2 High Tech. L.J. 369, 401 (1993). Indeed, NIH is by far the largest funding source for university-based research in the life sciences. *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 1, 35 n.109 (2002) (unpublished master copy), *available at* http://www.law.upenn.edu/fac/akrai/lcp.update.922.doc (last visited Dec. 20, 2002) (hereinafter Rai & Eisenberg, *Progress of Biomedicine*). It is no coincidence that 56 "of the 75 American Nobel laureates in physiology or medicine in the period from 1945-1998, . . . ha[ve] either worked at NIH or were supported by NIH prior to winning the prize." *Id.* (citation omitted).

One of the fundamental functions of non-commercial research is to verify and replicate the results of prior research. *See* Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q. J., 457, 470-71 (1989); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1048-55 (1989) (hereinafter Eisenberg, *Patents and the Progress of Science*). It is only through this peer review that scientific theories and discoveries gain credibility and vitality. *See id.*

Patents, however, now permeate many critical areas of scientific research. For instance, "[s]ome of the most important research tools in biotechnology [are] subject to proprietary restraints." Janice Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for*

Biomedical Research Tools, 76 Was. L. Rev. 1, 12 (2001). These patented inventions and processes include the technology used to create a "cre-loxP mouse," a mouse in which "a targeted gene is deleted when the cre gene encounters two loxP DNA segments bracketing the targeted gene;" the "Cohen-Boyer" method for gene cloning; the "oncomouse," which is a tumor-prone mouse useful as a model in cancer research; and human embryonic stem cells, "from which any type of human tissue can be grown." *Id.* at 12-14.

Not only are some of the basic building blocks to much of biotech research patented, but the increased tendency to patent innovation in this field has resulted in "a spiral of overlapping patent claims in the hands of different owners." Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 698 (1998) (hereinafter Heller & Eisenberg, *Anticommons*). This "proliferation of intellectual property rights" now allows each individual patent holder "to set up another tollbooth" delaying or even blocking further research innovation. *Id.* at 698-99.

Academic researchers did not face such "toll-booths" prior to the Federal Circuit's opinion in this case, largely because the universal assumption among universities and academic researchers was that the experimental use exception permitted non-profit researchers to conduct non-commercial experiments without regard to possible patent infringement. *See, e.g.*, John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation* 44 (Dec. 11, 2002) (unpublished draft on file with Petitioner); Rubenstein,

Promega Wins Round in European Patent Office, Legal Times, Aug. 2001, at 26; *see also* Barash, *supra*, at 697-99 (in general, scientists at non-profit institutions conduct research without engaging in patent background checks). The assumption that the experimental use exception protected universities engaging in non-commercial research from patent infringement claims was shared by legal commentators and even by some license holders. *See* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. Pat. and Trademark Off. Soc'y 617, 633 (1985) ("Few would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function."); Walsh, *supra*, at 44.

By eliminating the long-standing experimental use exception for universities and other non-profit research institutions, the Federal Circuit's opinion threatens substantial delay, further commercialization of non-profit research, and even the complete cessation of certain research projects. *See, e.g.*, Mueller, *supra*, at 7 ("[T]he stacking of intellectual property obligations as successive tools used in the course of an extended research project has the potential to impede or even preclude the development of new and better diagnostic and therapeutic products.") (citation omitted). As one commentator has noted, "'it is ludicrous to expect every researcher to obtain a license in advance of conducting a simple experiment, each time he sees a newly issued patent and attempts to duplicate the efforts in his laboratory.'" Barash, *supra*, at 698-99 (citation omitted). The Federal Circuit's opinion, however, may now require non-profit researchers to do just that. The failure to obtain permission to use patented materials may now result in pervasive and

costly litigation. *See* Rai & Eisenberg, *Progress of Biomedicine*, *supra*, at 14 n.45. As more and more patent holders begin to realize that they can extract high payment from universities or otherwise exploit non-profit innovations, the number of patent holders asserting rights against universities can be expected to rise dramatically.

The possibility that the patent system could stifle or even stymie the progress of biotechnology and other important fields of research is both real and profound. For instance, even if a university were willing to undertake an onerous background check of potential patents for its non-commercial experimentation, there may be so many patents underlying a contemplated research project that obtaining the necessary licenses becomes difficult or even impossible. *See* Heller & Eisenberg, *Anticommons*, *supra*, at 699-700. The transaction costs of obtaining these multiple licenses also may be prohibitively high. *See id.* at 700. In addition, a researcher may discover that one of the materials necessary for a contemplated research project is covered by a patent which has been exclusively licensed to another entity. *See id.* Such a scenario is not out of the question, even with respect to a fundamental research innovation. For example, human embryonic stem cells were recently patented by the Wisconsin Alumni Research Foundation ("WARF"). WARF then granted an exclusive license to use the cells to a commercial entity for commercial use. *See* Mueller, *supra*, at 14. Only after significant media attention did WARF reconsider its position and repudiate the license for three of the six cells. *See* Rai & Eisenberg, *Progress of Biomedicine*, *supra*, at 19 n.59. Without an experimental use exception, the existence of an

exclusive license would stop in its tracks any research conducted by a non-licensee.

An additional host of problems are certain to arise based on the inherent difficulty for researchers in identifying all patents potentially implicated by the course of their studies. Researchers are not always aware of the path their research might take and what materials may be necessary to continue with a particular line of inquiry. "Interrupting an ongoing research project to obtain a license to use a prior discovery that has unexpectedly proved relevant to the inquiry could cause wasteful delays." Eisenberg, *Patents and the Progress of Science*, *supra*, at 1056. Even worse, a discovery mid-stream that a requisite patented process has been exclusively licensed could bring a research project to a grinding halt.

The uncooperative patent holder who demands unreasonable returns in exchange for the right to use a particular patent is now also a significant threat. *See* Heller & Eisenberg, *Anticommons*, *supra*, at 699-701. The terms of a license may be unreasonable because the patent holder overvalues his patent or because the proposed terms unduly restrict the researcher's future actions. *See id.* at 701. Indeed, NIH strongly discourages researchers who use NIH funds from agreeing to reach-through royalty arrangements because they tend to hinder, rather than promote, the dissemination of scientific knowledge. *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,091, 72,093 (Dec. 23, 1999). The patent holder might also torpedo a non-profit research project through destructive negotiation tactics. *See* Heller & Eisenberg, *Anticommons*, *supra*, at 701.

For instance, in order to gain information about another researcher's project within the patent holder's field, the patent holder might demand that a researcher divulge confidential information about the contemplated project. A researcher, however, may rather forego a project than reveal too many of his original ideas to a potential rival. *See* Eisenberg, *Patents and the Progress of Science*, *supra*, at 1061-63.

Indeed, Dr. Madey's actions in this case demonstrate a university's vulnerability to the random whims of a patent holder. Dr. Madey allowed Duke to use his patents for years. Only when he became disgruntled with the University's decisions regarding leadership in the laboratory did he seek to enforce his alleged patent rights against Duke. (App. B, *infra*, at 35a-37a). If Dr. Madey prevails in this case, it will signal to other disgruntled patent holders as well as patent holders who do not agree with particular hypotheses or lines of research that they may effectively prevent others from undertaking contested research. *See* Eisenberg, *Patents and the Progress of Science*, *supra*, at 1054-55.

It is no comfort that, until now, most patent holders have failed to assert their patent rights against the non-profit research community. *See generally* David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 Hous. J. Int'l L. 615, 659 (1994); Hantman, *supra*, at 642. The dearth of lawsuits can be attributed, at least in part, to the recognized existence of the experimental use exception and the assumption within the science community that non-profit research enjoyed an exemption from patent infringement claims. *See id.* Moreover, even a single patent holder can significantly impede scientific progress. For instance, in 1991, Hoffman-La Roche (Roche) obtained patent rights to a thermostable enzyme Thermus aquaticus

YT1 DNA polymerase (Taq), which is a basic and widely used biotechnology tool for DNA sequencing, as well as rights to "the revolutionary DNA amplification process [utilizing] Taq." Mueller, *supra*, at 3. In accusing another company of selling Taq outside the license Roche sold to it, Roche "accused more than forty U.S. universities and research institutions (including Harvard, Stanford, Massachusetts Institute of Technology, the Salk Institute, the Scripps Research Institute, and the National Cancer Institute) and more than 200 individual scientists of infringing these patents." *Id.* While Roche never formally joined any of the research institutions or individual scientists in the lawsuit, its accusations "sent a chill through the research community." Rubenstein, *supra*, at 26. Now that the Federal Circuit has proclaimed the experimental use exception unavailable to research institutions, companies like Roche may be more likely to bring patent infringement claims against non-profit research institutions or their individual scientists. *See* Mueller, *supra*, at 3 (noting that Roche spokesperson warned that she "wouldn't want to predict" what future patent enforcement actions Roche might take against the scientific community).

Equally unsatisfying is the argument that patent holders will not aggressively assert their patent rights against universities because it is unpopular to do so, *see generally* Walsh et al., *supra*, at 45-46; Parker, *supra*, at 658-59, or because any potential damage from the non-commercial use of a patent is small, *see* Hantman, *supra*, at 642. Relying on the good will of the patent holder will not provide non-profit research institutions with the security or protection they need to go forward with lengthy and ground-breaking research projects. If universities are subject to liability for patent infringement when using a patent experimentally,

any holder of a patent on an important innovation might be able, at any time, to enjoin a university from using the patent; seek restrictive royalty reach-through agreements; or charge extremely high fees for licenses or other agreements. *See* Eisenberg, *Proprietary Rights*, *supra*, at 217-18; Heller & Eisenberg, *Anticommons*, *supra*, at 699-701. The threat of any of these actions can stifle the scope and creativity of a research project or — even worse — cause the project to be aborted altogether. This case provides a prime example of this potential danger. Dr. Madey asserted his patent rights against Duke only after employment disputes arose between him and the University. (App. B, *infra*, at 35a-37a). In addition, as patentees realize that universities are subject to patent infringement claims for any experimental use of a patent, they will undoubtedly seek to enforce their patent rights against such institutions.

Finally, the importance of having an experimental use exception remains, despite arguments that many infringing activities in laboratories are too isolated and innocuous to attract the attention of a patent holder. *See generally* Michelle Walters, *De Minimis Use and Experimental Use Exceptions to Patent Infringement: A Comment on the* Embrex *Concurrence*, 29 AIPLA Q. J. 509, 539 (2001). It is no solution to the dilemma presented by the elimination of the experimental use exception to expect the scientific community simply to violate the law. *See* Rai & Eisenberg, *Progress of Biomedicine*, *supra*, at 14 n.45 (noting that "one might question the long-term viability of a solution that is based on pervasive law-breaking that may yet trigger costly litigation when it comes to light"). Universities are not scofflaws, and they cannot be expected to advise students and faculty to violate the law.

Scientific progress is essential to the health of our Nation. The very fabric of scientific method depends on the ability of scientists to build upon the discoveries of those who have gone before them. *See* Eisenberg, *Patents and the Progress of Science*, *supra*, at 1055-60. As Sir Isaac Newton famously proclaimed, "If I have seen further, it is by standing on the shoulders of giants." *Id.* at 1055. Thus, universities and other non-profit institutions must be able to access prior information in their fields to further knowledge and promote science.

Until the Federal Circuit's opinion in this case, "[t]he experimental use doctrine offer[ed] a potential mechanism for reconciling the patent monopoly with the interest of the research community . . . ." Eisenberg, *Proprietary Rights*, *supra*, at 230. Without the exception, patent law is certain to have a substantial chilling effect on the course of future non-profit research. The Court should review this case to restore the experimental use exception for non-profit research institutions, thereby allowing researchers safely to conduct important and potentially life-saving research.

CONCLUSION

The Court should grant the petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit.

Respectfully Submitted,

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED OCTOBER 3, 2002

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

01-1567

JOHN M.J. MADEY,

Plaintiff-Appellant,

v.

DUKE UNIVERSITY,

Defendant-Appellee.

DECIDED: October 3, 2002

Before BRYSON, GAJARSA, and LINN, *Circuit Judges.*

GAJARSA, *Circuit Judge.*

Dr. John M.J. Madey ("Madey") appeals from a judgment of the United States District Court for the Middle District of North Carolina. Madey sued Duke University ("Duke"), bringing claims of patent infringement and various other federal and state law claims. Pursuant to a motion filed by Duke under Federal Rule of Civil Procedure ("FRCP") 12(b)(1), the district court dismissed-in-part certain patent infringement claims and dismissed certain other claims. *Madey v. Duke Univ.*, No. 1:97CV1170, slip op. at 12-14,

38-40 (M.D.N.C. Dec. 1, 1999) ("*Dismissal Opinion*"). After discovery, the district court granted summary judgment in favor of Duke on the remaining claims. For a first set of alleged infringing acts, it held that the experimental use defense applied to Duke's use of Madey's patented laser technology. For a second set of alleged infringing acts, it held that Duke was not the infringing party because a third-party owned and controlled the allegedly infringing laser equipment. *Madey v. Duke Univ.*, No. 1:97CV1170, slip op. at 12-15, 18, 20 (M.D.N.C. June 15, 2001) ("*Summary Judgment Opinion*"). The district court erred in its partial dismissal, erred in applying the experimental use defense, but, for the second set of alleged infringing acts, correctly determined that Duke did not infringe because it did not own or control the equipment. Accordingly, we reverse-in-part, affirm-in-part, and remand.

I. BACKGROUND

In the mid-1980s Madey was a tenured research professor at Stanford University. At Stanford, he had an innovative laser research program, which was highly regarded in the scientific community. An opportunity arose for Madey to consider leaving Stanford and take a tenured position at Duke. Duke recruited Madey, and in 1988 he left Stanford for a position in Duke's physics department. In 1989 Madey moved his free electron laser ("FEL") research lab from Stanford to Duke. The FEL lab contained substantial equipment, requiring Duke to build an addition to its physics building to house the lab. In addition, during his time at Stanford, Madey had obtained sole ownership of two patents practiced by some of the equipment in the FEL lab.

Appendix A

At Duke, Madey served for almost a decade as director of the FEL lab. During that time the lab continued to achieve success in both research funding and scientific breakthroughs. However, a dispute arose between Madey and Duke. Duke contends that, despite his scientific prowess, Madey ineffectively managed the lab. Madey contends that Duke sought to use the lab's equipment for research areas outside the allocated scope of certain government funding, and that when he objected, Duke sought to remove him as lab director. Duke eventually did remove Madey as director of the lab in 1997. The removal is not at issue in this appeal, however, it is the genesis of this unique patent infringement case. As a result of the removal, Madey resigned from Duke in 1998. Duke, however, continued to operate some of the equipment in the lab. Madey then sued Duke for patent infringement of his two patents, and brought a variety of other claims.

A. The Patents and Infringing Equipment

One of Madey's patents, U.S. Patent No. 4,641,103 ("the '103 patent"), covers a "Microwave Electron Gun" used in connection with free electron lasers. The other patent, U.S. Patent No. 5,130,994 ("the '994 patent"), is titled "Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution And Fast Time Resolution Spectroscopy." The details of these two patents are not material to the issues on appeal. Their use in the lab, however, as embodied in certain equipment, is central to this appeal.

Appendix A

The equipment at the Duke FEL lab that practices the subject matter disclosed and claimed in the patents is set forth in the list below, which first lists the equipment and then the patent(s) it embodies.

- An infrared FEL called the "Mark III FEL," embodying the '994 patent and the '103 patent (by incorporating the microwave electron gun in the infrared FEL).

- A "Storage Ring FEL," embodying the same patents as the Mark III FEL because it incorporates a Mark III FEL.

- A "Microwave Gun Test Stand," embodying the '103 patent (by incorporating the microwave electron gun).

The three alleged infringing devices are the Mark III FEL, the Storage Ring FEL, and the Microwave Gun Test Stand. Although it is not clear from the record, perhaps because Duke defended by asserting experimental use and government license defenses, Duke seems to concede that the alleged infringing devices and methods read on the claims of the patents. Although the three devices were housed in Duke's physics facilities, the Microwave Gun Test Stand was not Duke's asset, but rather belonged to North Carolina Central University ("NCCU").

Appendix A

B. Duke's Relationship with NCCU

Madey and Duke built the Microwave Gun Test Stand as a subcontractor to NCCU after the government awarded NCCU a contract to study microwave guns (the "AFOSR Contract"). Professor Jones of NCCU was the principal investigator under this government project. The Microwave Gun Test Stand was built and housed in the Duke FEL lab. The AFOSR Contract listed the Microwave Gun Test Stand as NCCU's asset.

C. The District Court's Dismissal Opinion

Duke moved to dismiss the infringement claims under the '103 patent under both FRCP 12(b)(1) for lack of subject matter jurisdiction, and under FRCP 12(b)(6) for failure to state a claim upon which relief can be granted. *Dismissal Opinion* at 9 n.2. The district court granted the first motion in part, but denied the second motion. Madey alleges on appeal that the district court erred in its FRCP 12(b)(1) partial dismissal.

Motion to Dismiss under FRCP 12(b)(1)

The district court reasoned that Duke's alleged unauthorized use of the '103 patent fell into two categories: (i) use in furtherance of an Office of Naval Research ("ONR") grant; and (ii) use that exceeds the authorized scope of the ONR grant. The district court determined that if all the unauthorized use fell in the first category, jurisdiction would lie in the Court of Federal Claims. On the other hand, if all of the unauthorized use fell in the second category,

jurisdiction would lie in federal district court. In all probability, however, the use spanned both categories.

To make the determination as to whether dismissal under FRCP 12(b)(1) was proper, the district court relied on 28 U.S.C. § 1498(a), set forth below.

> (a) Whenever an invention described in and covered by a patent of the United States is *used or manufactured by or for the United States* without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .
>
> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation *for the Government and with the authorization or consent of the Government*, shall be construed as use or manufacture for the United States. . . .

28 U.S.C. § 1498(a) (2000) (emphasis added).

The district court reasoned that under § 1498(a) Madey must sue in the Court of Federal Claims for any use in furtherance of the ONR grant. *Dismissal Opinion* at 10-11. This reasoning assumes that the ONR grant provides the

"authorization or consent" of the government to be sued, and designates Duke's use as "by or for" the United States. The district court did not, however, discuss or analyze the particular statements or aspects of the ONR grant that provided the government's authorization or consent to be sued. Nor did the court discuss or characterize Duke's use or manufacture as "by or for the United States."

The district court acknowledged that the use at issue was potentially mixed between the two categories, within the scope of the ONR grant, and without. The district court applied Fourth Circuit law, under which the burden of proving subject matter jurisdiction is with the plaintiff. *Id.* at 11 (quoting *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991)). Thus, even at the pleading stage, according to the district court, the nonmoving party must set forth evidence of specific "jurisdictional" facts to show that a genuine issue of material fact exists; the moving party prevails only if the material jurisdictional facts are not in dispute. *Id.* (citing *Trentacosta v. Frontier Pac. Aircraft Indus.*, 813 F.2d 1553, 1558 (9th Cir. 1987)).

The district court rejected Duke's contention that even if only some use is for the government, the claim should be dismissed. The court noted that the extent of Duke's "use of the '103 patent for private purposes is unclear." *Id.* at 13. The court acknowledged that discovery would be necessary to determine the nature and extent of Duke's private use. However, for Duke's use of the patents "under the authority

of the government research grant," the district court dismissed Madey's claim without prejudice.[1]

D. The District Court's Summary Judgment Opinion

Among Duke's motions for summary judgment, two are relevant on appeal, entitled by the district court as: (i) the "Patent Motion;" and (ii) the "Test Stand Gun Motion."

The Patent Motion and the Experimental Use Defense

The district court acknowledged a common law "exception" for patent infringement liability for uses that, in the district court's words, are "solely for research, academic or experimental purposes." *Summary Judgment Opinion* at

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1. The district court also ruled on various other motions to dismiss. First, it granted a motion by a number of individual defendants named with Duke to dismiss Madey's claims against them pursuant to FRCP 8, 9(b) and 12(b)(6). *Dismissal Opinion* at 6. Specifically, without reaching the merits of Rule 9(b) or Rule 12(b)(6), the district court dismissed Madey's claims against the individual defendants under Rule 8 because the claims did not provide sufficient notice to the individual defendants. *Id.* at 7-8. Madey has not appealed this dismissal.

Second, the district court denied Duke's motions to dismiss Madey's claims for conversion of property, *id.* at 16, misappropriation of business opportunities, *id.* at 21, constructive fraud, *id.* at 33, and breach of contract, *id.* at 38. However, the court granted Duke's motions to dismiss Madey's age discrimination claims, *id.* at 27, and civil rights claims, *id.* at 30. Madey has not appealed the district court's grant of these last two motions.

9 (citing *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631, 14 USPQ2d 1636, 1642 (1990); *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); and citing two commentators[2]). The district court recognized the debate over the scope of the experimental use defense, but cited this court's opinion in *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349, 55 USPQ2d 1161, 1163 (Fed. Cir. 2000) to hold that the defense was viable for experimental, non-profit purposes. *Summary Judgment Opinion* at 9 (citing *Embrex*, 216 F.3d at 1349, 55 USPQ2d at 1163 (noting that courts should not "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes" (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863, 221 USPQ 937, 940 (Fed. Cir. 1984))[3])).

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2. Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 17 (2001); 5 *Chisum on Patents* § 16.03[1] (2000).

3. The accused infringer in *Roche* sought to assert the experimental use defense to allow early development of a generic drug. After the *Roche* decision, however, Congress changed the law, overruling *Roche* in part, but without impacting the experimental use doctrine. Congress provided limited ability for a company to practice a patent in furtherance of a drug approval application. *See Deuterium*, 19 Cl. Ct. at 632 n.14, 14 USPQ2d at 1642 n.14.

Appendix A

After having recognized the experimental use defense, the district court then fashioned the defense for application to Madey in the passage set forth below.

> Given this standard [for experimental use], for [Madey] to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue "solely for an experimental or other non-profit purpose." 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000). More specifically, [Madey] must sufficiently establish that [Duke's] use of the patent had "definite, cognizable, and not insubstantial commercial purposes." *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856, 863 (1984).

Summary Judgment Opinion at 10.

On appeal, Madey attacks this passage as improperly shifting the burden to the plaintiff to allege and prove that the defendant's use was not experimental.

Before the district court, Madey argued that Duke's research in its FEL lab was commercial in character and intent. *Id.* Madey relied on *Pitcairn v. United States*, 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976), where the government used patented rotor structures and control systems for a helicopter to test the "lifting ability" and other attributes of the patented technology. *Pitcairn*, 547 F.2d at 1125-26, 192 USPQ at 625. The *Pitcairn* court held that the helicopters were not built solely for experimental purposes because they were also built to benefit the government in its legitimate business. *Id.* Based on language in Duke's patent

policy, Madey argues that Duke is in the business of "obtaining grants and developing possible commercial applications for the fruits of its 'academic research.' " *Summary Judgment Opinion* at 11.

The district court rejected Madey's argument, relying on another statement in the preamble of the Duke patent policy which stated that Duke was "dedicated to teaching, research, and the expansion of knowledge . . . [and] does not undertake research or development work principally for the purpose of developing patents and commercial applications." *Id.* The district court reasoned that these statements from the patent policy refute any contention that Duke is "in the business" of developing technology for commercial applications. *Id.* at 12. According to the district court, Madey's "evidence" was mere speculation,[4] and thus Madey did not meet his burden of proof to create a genuine issue of material fact.[5]

4. Madey also argued that Duke's acceptance of funding from the government and private foundations was evidence of developing patented devices with commercial intent. The district court also rejected this proposition. *Summary Judgment Opinion* at 13 (citing *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935) (concluding that the experimental use defense applies when a university uses a patented device in furtherance of its educational purpose); Ronald D. Hartman, *Experimental Use as an Exception to Patent Infringement*, 67 J. Pat. Off. Soc'y 617, 633 (1985) (concluding that *Ruth* supports application of the experimental use defense to a university's operations in furtherance of its educational function)).

5. The district court discussed and dismissed in a footnote other evidence suggested by Madey, including the fact that Duke had established (but not yet applied) an hourly fee for industrial users wishing to use the FEL lab's resources, and statements from Duke's website for the FEL lab indicating an interest in corporate partnerships. *Id.* at 15 n.2.

Id. The court went on to state that "[w]ithout more concrete evidence to rebut [Duke's] stated purpose with respect to its research in the FEL lab, Plaintiff has failed to meet its burden of establishing patent infringement by a preponderance of the evidence." *Id.* at 13.

Finally, under its discussion of the Patent Motion, the district court reasoned that Duke's argument that "essentially all" uses of the patents were covered by a license to the government was moot given the experimental use holding. Despite its mootness determination, the district court went on to partially analyze the government license issue as set forth in the passage below.[6] *Id.* at 16.

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6. In a footnote, the district court cites to a section from the Bayh-Dole Act to support its reasoning that the government has a license to have patents practiced on its behalf when the government contributed to the funding of such patents. *Id.* at 16 n.3 (citing 35 U.S.C. § 202(c)(4) (2000)). The relevant section is set forth below.

> (c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:
>
> . . .
>
> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . .

35 U.S.C. § 202(c)(4) (2000).

(Cont'd)

> The Court does note, however, as it did previously when ruling upon [Duke's] Motion to Dismiss, that all uses that have been made of the patented devices that are covered by such a license are not subject to infringement liability.

Id.

The Test Stand Gun Motion

Under the Test Stand Gun Motion, Duke argued that any use of the patented equipment before June 1997 is not infringement because Madey consented to the manufacture and use of the Microwave Gun Test Stand by Duke and NCCU before this date. The district court agreed, concluding that

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(Cont'd)

The district court stated that the "funding agreements for the inventions created under the '994 and '103 patents expressly provide that the Government retained rights in those inventions." *Id.* Thus, the district court reasoned, in light of the Bayh-Dole Act, Duke's use of the patents that has been authorized by the government does not constitute patent infringement. Finally, the district court noted that:

> [a]lthough the parties have presented conflicting evidence as to the extent to which the patented devices have been used for a purpose consented to by the Government, because [Madey] has failed to create a genuine issue of material fact as to whether [Duke] has commercially benefited or intends to do so with respect to the patents at issue, the uses that have been made to date with respect to both patents are, at this point, exempt from infringement liability.

Id.

there was no infringement before such date because Madey approved of such use via his direct involvement. *Summary Judgment Opinion* at 17. Madey does not appeal this issue.

After June 1997, however, Duke's defense is that no one affiliated with Duke used the Microwave Gun Test Stand. Duke relied on attestations by Dr. Jones, the NCCU professor who was the principal investigator for the AFOSR contract. The district court determined that Dr. Jones was not an agent of Duke. *Id.* at 19-20. It also determined that Dr. Jones controlled physical access to the Microwave Gun Test Stand because he had the key switch to operate the device. *Id.* at 18. The district court held any contrary assertions by Madey to be "bald allegations and mere speculation." *Id.* at 19.

Given Dr. Jones' attestation that he was unaware of any Duke faculty members or employees using the Microwave Gun Test Stand after June 1997, the district court determined that there was no genuine issue of material fact and awarded summary judgment of no infringement to Duke on this issue. *Id.* at 20.

Supplemental Jurisdiction of Madey's State Law Claims

At the conclusion of its *Summary Judgment Opinion*, the district court noted that four state law claims remained in the case: conversion of property, misappropriation of business opportunities, constructive fraud, and breach of contract. *Id.* at 20 n.6. Given its determination on the two patent infringement motions, the district court declined to exercise supplemental jurisdiction over the outstanding state law claims and dismissed them without prejudice. *Id.* at 21.

Appendix A

II. DISCUSSION

A. Standard of Review

We review a district court's grant of summary judgment without deference. *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1378, 53 USPQ2d 1225, 1227 (Fed. Cir. 1999). Summary judgment is appropriate when the moving party demonstrates that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FRCP 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). On summary judgment, the evidence must be viewed in the light most favorable to the party opposing the motion, *Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962), with doubts resolved in favor of the nonmovant, *Cantor v. Detroit Edison Co.*, 428 U.S. 579 (1976); *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274, 35 USPQ2d 1035, 1038 (Fed. Cir. 1995). Once the moving party has satisfied its initial burden, the opposing party must establish a genuine issue of material fact and cannot rest on mere allegations, but must present actual evidence. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Issues of fact are genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* A disputed fact is material to the outcome of the suit if a finding of that fact is necessary and relevant to the proceeding. *Id.*; *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 980, 41 USPQ2d 1440, 1442 (Fed. Cir. 1997).

We review questions of patent law *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169,

1172 (Fed. Cir. 1998) (en banc). The determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353, 48 USPQ2d 1674, 1676 (Fed. Cir. 1998). On procedural issues, this Court follows the rule of the regional circuit, unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit. *See Nat'l Presto v. W. Bend Co.*, 76 F.3d 1185, 1188 n.2, 37 USPQ2d 1685, 1686 n.2 (Fed. Cir. 1996). Accordingly:

> [w]e apply regional circuit law to procedural issues that are not themselves substantive patent law issues so long as they do not (1) pertain to patent law, *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1365, 57 USPQ2d 1635, 1637 (Fed. Cir. 2001) ("We will apply our own law to both substantive and procedural issues 'intimately involved in the substance of enforcement of the patent right' " (citation omitted)), (2) bear an essential relationship to matters committed to our exclusive control by statute, or (3) clearly implicate the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359, 50 USPQ2d 1672, 1675 (Fed. Cir. 1999) (en banc in relevant part).

Int'l Nutrition Co. v. Horphag Research Ltd., 257 F.3d 1324, 1328, 59 USPQ2d 1532, 1535 (Fed. Cir. 2001).

Review of the district court's interpretation of the experimental use defense and its proper scope are questions of law and statutory interpretation that are reviewed *de novo*. *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1381, 49 USPQ2d 1144, 1146 (Fed. Cir. 1998). A dismissal for lack of subject matter jurisdiction is a procedural question not unique to patent law, therefore we follow the law of the regional circuit. *Molins PLC v. Quigg*, 837 F.2d 1064, 1066, 5 USPQ2d 1526, 1527 (Fed. Cir. 1988) (explaining that justiciability in the district court does not pertain to patent law and thus follows regional circuit law). The United States Court of Appeals for the Fourth Circuit reviews *de novo* a dismissal under FRCP 12(b)(1). *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999).

B. The District Court's Dismissal Opinion

On appeal, Madey argues that the district court improperly applied 28 U.S.C § 1498(a) by failing to make sufficient supporting determinations. As a result, according to Madey, partial dismissal of the '103 patent infringement claim for Duke's use under the ONR grant was improper. Specifically, Madey argues that the court did not find that Duke's use was "by or for the United States," and that the use was with the "authorization or consent" of the United States. Madey makes the distinction that a research grant is different from a contract to acquire property or services for the government. Duke, on the other hand, attacks Madey's distinction as meaningless, arguing that either a grant or a contract can meet the prerequisites of § 1498(a).

Based on the district court's findings, we agree with Madey that the district court erred in granting the partial dismissal. Madey, however, also asserts that a research grant can never meet the requirements of § 1498(a). We disagree with this proposition.

The district court did not clearly identify, discuss or analyze the particular statements or aspects of the ONR grant that may have provided the government's authorization or consent to be sued. The court seems to have assumed that a research grant by a federal agency to a university for financial support of scientific research proposed by the university constitutes activity "for the United States" and provides authorization or consent by the United States for patent infringement liability for any patents used in the course of the research. In addition, the court did not discuss or characterize Duke's use or manufacture of the '103 patent embodiments as "by or for the United States."

In general, there are two important features of § 1498(a). It relieves a third party from patent infringement liability, and it acts as a waiver of sovereign immunity and consent to liability by the United States. *See Crater Corp. v. Lucent Tech., Inc.*, 255 F.3d 1361, 1364, 59 USPQ2d 1044, 1045 (Fed. Cir. 2001) ("If a patented invention is used or manufactured for the government by a private party, that private party cannot be held liable for patent infringement."); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554-55 & n.6, 16 USPQ2d 1587, 1595-96 & n.6 (Fed. Cir. 1990) (discussing § 1498(a) in two contexts, when raised by a private party as a defense, in which case it is not jurisdictional, and when invoked in a suit against the United

States, in which case it is jurisdictional) (citing for support and discussing *Sperry Gyroscope Co. v. Arma Eng'g Co.*, 271 U.S. 232, 235-36 (1926)). Waivers of sovereign immunity are to be strictly construed. *See, e.g., Irwin v. Dep't of Veterans Affairs*, 498 U.S. 89, 94 (1990); *Library of Congress v. Shaw*, 478 U.S. 310, 318 (1986). This general mantra influences the application of § 1498(a) between private parties because in such a situation § 1498(a) is an affirmative defense. *Manville*, 917 F.2d at 555 & n.6, 16 USPQ2d at 1595-96 & n.6. As a result, one possible consequence of dismissal based on this defense is a suit against the government in the Court of Federal Claims. *Id.* at 555 & n.8, 16 USPQ2d at 1596 & n.8. In the sphere of this sovereign immunity influence on the defense, the teachings of *Crater* and *Manville* illustrate two errors by the district court in dismissing the claims for Duke's use of the '103 patent under the ONR grant.

First, the district court relied on the doctrine of jurisdictional facts when, as between private parties, § 1498(a) is not jurisdictional. *Id.* at 555 & n.6, 16 USPQ2d at 1595-96 & n.6. The district court applied the Fourth Circuit's general jurisdictional facts doctrine. This is error because Federal Circuit law provides the applicable interpretation of § 1498(a). Section 1498(a) applies exclusively to patent law, meaning that Federal Circuit law applies. *Nat'l Presto*, 76 F.3d at 1188 n.2, 37 USPQ2d at 1686 n.2. One might counter-argue that § 1498(a) is procedural. However, to the extent that § 1498(a) is procedural, it is unique to patent law, which also indicates that Federal Circuit law applies. *Id.* Federal Circuit law, under *Crater* and *Manville*, teaches that § 1498(a) is an affirmative

defense and is not jurisdictional. *Crater*, 255 F.3d at 1364, 59 USPQ2d at 1045; *Manville*, 917 F.2d at 555 & n.6, 16 USPQ2d at 1595-96 & n.6. Because § 1498(a) is not jurisdictional, the jurisdictional facts doctrine does not apply. Therefore, the basis for the district court's partial dismissal was improper.

Second, by failing to explain or demonstrate precisely how the ONR grant authorizes the government's consent to suit or authorizes Duke to use or manufacture the patented articles for the government, the district court has provided no findings or analysis upon which we can base our review of the issue appealed from the court's *Dismissal Opinion*. Although a research grant may not meet the requirements of § 1498(a), from the limited record presented by the parties, it cannot be determined whether the ONR grant may authorize the necessary predicates for § 1498(a). However, even if Duke ultimately prevails on its assertion of § 1498(a) as an affirmative defense for its use of the '103 patent under the ONR grant, that does not mean that the district court's dismissal of the claim was without error. The ultimate factual and liability determinations are issues for the district court to determine initially on remand because in addition to evaluating the ONR grant and making the requisite findings, as it noted in its *Dismissal Opinion*, it has not yet determined which uses fall within the scope of the ONR grant and which uses are outside that scope. *See Dismissal Opinion* at 13. This determination, as well, seems necessary to support the dismissal in-part.

Appendix A

C. The District Court's Application of Experimental Use

On appeal, Madey asserts three primary errors related to experimental use. First, Madey claims that the district court improperly shifted the burden to Madey to prove that Duke's use was not experimental. Second, Madey argues that the district court applied an overly broad version of the very narrow experimental use defense inconsistent with our precedent. Third, Madey attacks the supporting evidence relied on by the district court as overly general and not indicative of the specific propositions and findings required by the experimental use defense, and further argues that there is no support in the record before us to allow any court to apply the very narrow experimental use defense to Duke's ongoing FEL lab operation. We substantially agree with Madey on all three points. In addition, Madey makes a threshold argument concerning the continued existence of the experimental use doctrine in any form, which we turn to first. Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form.

The Experimental Use Defense

Citing the concurring opinion in *Embrex*, Madey contends that the Supreme Court's opinion in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) eliminates the experimental use defense. *Embrex*, 216 F.3d at 1352-53, 55 USPQ2d at 1166-67 (Rader, J., concurring). The Supreme Court held in *Warner-Jenkinson* that intent plays no role in the application of the doctrine of equivalents. *Warner-Jenkinson*, 520 U.S. at 36. Madey implicitly argues

that the experimental use defense necessarily incorporates an intent inquiry, and thus is inconsistent with *Warner-Jenkinson*. Like the majority in *Embrex*, we do not view such an inconsistency as inescapable, and conclude the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*, 216 F.3d at 1349, 55 USPQ2d at 1163, and in *Roche*, 733 F.2d at 863, 221 USPQ at 940.

The District Court Improperly Shifted the Burden to Madey

As a precursor to the burden-shifting issue, Madey argues that the experimental use defense is an affirmative defense that Duke must plead or lose. We disagree. Madey points to no source of authority for its assertion that experimental use is an affirmative defense. Indeed, we have referred to the defense in a variety of ways. *See Roche*, 733 F.2d at 862, 221 USPQ at 939-40 (referring to experimental use as both an exception and a defense). Given this lack of precise treatment in the precedent, Madey has no basis to support its affirmative defense argument. The district court and the parties in the present case joined the issue during the summary judgment briefing. We see no mandate from our precedent, nor any compelling reason from other considerations, why the opportunity to raise the defense if not raised in the responsive pleading should not also be available at the later stages of a case, within the procedural discretion typically afforded the trial court judge.

The district court held that in order for Madey to overcome his burden to establish actionable infringement, he must establish that Duke did not use the patent-covered

free electron laser equipment solely for experimental or other non-profit purposes. *Summary Judgment Opinion* at 10. Madey argues that this improperly shifts the burden to the patentee and conflates the experimental use defense with the initial infringement inquiry.

We agree with Madey that the district court improperly shifted the burden to him. The district court folded the experimental use defense into the baseline assessment as to whether Duke infringed the patents. Duke characterizes the district court's holding as expressing the following sequence: first, the court recognized that Madey carried his burden of proof on infringement; second, the court held that Duke carried its burden of proof on the experimental use defense; and third, the court held that Madey was unable to marshal sufficient evidence to rebut Duke's shifting of the burden. We disagree with Duke's reading of the district court's opinion. *See Summary Judgment Opinion* at 8-14. The district court explicitly contradicts Duke's argument by stating that Madey failed to "meet its burden to establish patent infringement by a preponderance of the evidence." *Id.* at 13. This statement is an assessment of whether Madey supported his initial infringement claim. It is not an assessment of which party carried or shifted the burden of evidence related to the experimental use defense. Thus, the district court did not conclude that Madey failed to rebut Duke's assertion of the experimental use defense. Instead, it erroneously required Madey to show as a part of his initial claim that Duke's use was not experimental. The defense, if available at all, must be established by Duke.

Appendix A

The District Court's Overly Broad Conception of Experimental Use

Madey argues, and we agree, that the district court had an overly broad conception of the very narrow and strictly limited experimental use defense. The district court stated that the experimental use defense inoculated uses that "were solely for research, academic, or experimental purposes," and that the defense covered use that "is made for experimental, non-profit purposes only." *Id.* at 9. Both formulations are too broad and stand in sharp contrast to our admonitions in *Embrex* and *Roche* that the experimental use defense is very narrow and strictly limited. In *Embrex*, we followed the teachings of *Roche* and *Pitcairn* to hold that the defense was very narrow and limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Embrex*, 216 F.3d at 1349, 55 USPQ2d at 1163. Further, use does not qualify for the experimental use defense when it is undertaken in the "guise of scientific inquiry" but has "definite, cognizable, and not insubstantial commercial purposes." *Id.* (quoting *Roche*, 733 F.2d at 863, 221 USPQ at 941). The concurring opinion in *Embrex* expresses a similar view: use is disqualified from the defense if it has the "slightest commercial implication." *Id.* at 1353, 55 USPQ2d at 1166. Moreover, use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense. *See Pitcairn*, 547 F.2d at 1125-26, 192 USPQ at 625. The district court supported its conclusion with a citation to *Ruth v. Stearns-Roger Mfg. Co.*, 12 F. Supp. 697, 713 (D. Colo. 1935), a case that is not binding precedent for this court.

Appendix A

The *Ruth* case represents the conceptual dilemma that may have led the district court astray. Cases evaluating the experimental use defense are few, and those involving non-profit, educational alleged infringers are even fewer. In *Ruth*, the court concluded that a manufacturer of equipment covered by patents was not liable for contributory infringement because the end-user purchaser was the Colorado School of Mines, which used the equipment in furtherance of its educational purpose. *Id.* Thus, the combination of apparent lack of commerciality, with the non-profit status of an educational institution, prompted the court in *Ruth*, without any detailed analysis of the character, nature and effect of the use, to hold that the experimental use defense applied. *Id.* This is not consistent with the binding precedent of our case law postulated by *Embrex*, *Roche* and *Pitcairn*.

Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

In the present case, the district court attached too great a weight to the non-profit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives.[7] On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense. The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

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7. Duke's patent and licensing policy may support its primary function as an educational institution. *See Duke University Policy on Inventions, Patents, and Technology Transfer* (1996), *available at http:// www.ors.duke.edu/policies/patpol.htm* (last visited Oct. 3, 2002). Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream. *See id.*

Appendix A

D. The District Court's Analysis of the Test Stand Gun Motion

In contrast to our conclusion that the district court erred in its dismissal-in-part of the alleged '103 patent infringement and its application of the experimental use defense, we find no error in the court's summary judgment conclusion that there is no genuine issue of material fact concerning Duke's non-use of the NCCU Microwave Gun Test Stand during the relevant time period.

Specifically, the district court found that NCCU, through the subcontractor agreement it had with Duke, owned the Microwave Gun Test Stand, and that Dr. Jones of NCCU controlled the gun with a key switch. Even though the gun was located on Duke's premises, Dr. Jones stated that no Duke faculty member or employee had used the gun during the relevant time period. This evidence of ownership, control, and no known Duke use, is sufficient to shift the summary judgment burden to Madey, who, in the district court's words, offers in response only bare allegations and speculation. Most of the response is testimony by Madey himself.

Madey contends that Duke and Dr. Jones have tacitly admitted to disputed questions of fact concerning whether Duke had any control or benefit over the Microwave Gun Test Stand. In addition, Madey contends that joint publications by Dr. Jones and Duke faculty, as well as research interests held by Duke faculty in areas potentially implicated by the Microwave Gun Test Stand, demonstrate disputed material facts about Duke's benefit and influence over the gun. Like the district court, we do not find that the

record supports Madey's contentions, nor do we concur in the inferences in which Madey would have us draw. *See Anderson*, 477 U.S. at 248 (explaining that a party cannot create a genuine issue of material fact based on mere allegations, but must present actual evidence); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206-07, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (explaining that the patent-holder's alleged inferences were mere speculation and thus not supportable).

In addition, we note that the record does not indicate that Madey plead any vicarious liability claims, such as alleging that Duke induced NCCU's infringement, or contributory infringement claims. To the extent that this was a strategic decision or tactical choice on Madey's part, he should not be allowed to overcome this choice now by acceptance of allegations and speculation as genuine issues of material fact.

E. Additional Matters

Finally, we note two additional matters in response to the parties' arguments before us and for the district court's attention on remand.

Duke's Assertion of a Government License Defense

Before this court, Duke argued vehemently that even if we did not agree with the district court's application of the experimental use defense that we could affirm the district court's judgment on alternate grounds: that the government had a license to have the patents at issue practiced on its

behalf. We disagree with Duke's assertion because it overstates the information contained in the record on appeal. The only concrete evidence Duke cites is the statements on each of the patents noting that the government has rights in the patents. This, however, is insufficient because these short notations on the patents do not define the scope of the government's rights. None of the controlling contracts that would define the scope of such rights are provided in the record nor discussed by Duke in its arguments.

In addition, Duke discusses at length the Bayh-Dole Act, urging that this provides a basis to conclude that the scope of the rights granted to the government encompass Duke's use. Madey, however, notes that the provisions cited by Duke were enacted into law after Madey's two patents issued. Thus, some other provision may have generated the "government rights" notation on the two patents. In sum, this discussion serves to illustrate that the government license issue needs further development before the district court if it is to ultimately provide Duke the defense it seeks.

The District Court's Supplemental Jurisdiction Determination

At the end of its *Summary Judgment Opinion*, the district court declined to exercise supplemental jurisdiction over four state law claims remaining in the case: conversion of property, misappropriation of business opportunities, constructive fraud, and breach of contract. *Summary Judgment Opinion* at 20 n.6. On remand, given our reversal of the district court's application of the experimental use defense, these claims are still initially available to Madey.

III. CONCLUSION

The district court erred in its application of the common law experimental use defense, and, consequently, incorrectly found that there was no genuine issue of material fact upon which Madey could prevail. In addition, the court's dismissal-in-part of Duke's use of the '103 patent embodiments under the government ONR grant was in error. Due to these errors, further proceedings are necessary. This includes the opportunity for the district court to reevaluate the issues we remand in light of this opinion, for the parties to litigate Duke's asserted government license defense, and for the court to potentially consider the state law claims in accordance with the case's progression. Accordingly, we affirm-in-part and reverse-in-part the district court's decision and remand for additional proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED.

COSTS

No costs.

APPENDIX B — MEMORANDUM OPINION AND ORDER AND JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA DATED AND FILED JUNE 15, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

1:97CV01170

JOHN M. J. MADEY,

Plaintiff,

v.

DUKE UNIVERSITY,

Defendant.

MEMORANDUM OPINION

BEATY, District Judge.

This matter is presently before the Court on Defendant Duke University's motions for partial summary judgment. Specifically, Defendant has submitted the following motions for consideration in response to Plaintiff's claims: (1) a Motion for Partial Summary Judgment of Non-Infringement of the '103 and '994 Patents Based on Government License ("Patent Motion") [Document # 65]; (2) a Motion for Partial Summary Judgment of Non-Infringement with Respect to the NCCU Test Stand

Gun ("Test Stand Gun Motion") [Document # 60]; and (3) a Motion for Partial Summary Judgment on the State Law Claims ("State Law Motion") [Document # 63]. For the reasons that follow, Defendant's Patent Motion and Defendant's Test Stand Gun Motion are GRANTED. In view of the Court's decision with respect to these motions, the Court will decline to exercise supplemental jurisdiction over Plaintiff's state law claims. Accordingly, Defendant's State Law Motion is not addressed by this Memorandum Opinion.

I. FACTS AND PROCEDURAL BACKGROUND

Plaintiff John M. J. Madey ("Plaintiff" or "Dr. Madey") is an internationally known scientist and scholar in the field of electromagnetic radiation and its uses. Dr. Madey was hired by Defendant Duke University ("Defendant", "Duke", "the University") in 1989 as a professor, primarily to assist the University in establishing a Free Electron Laser Laboratory ("FEL Lab") and research program. Before coming to Duke, Plaintiff secured United States Patent Number 4,641,103 for the microwave electron guns now used in the FEL Lab ("103 Patent"). Plaintiff is also the co-owner and exclusive patent holder for United States Patent Number 5,130,994 ("994 Patent"), the patent that covers the Mark III, a Free Electron Laser that is also currently in use in the FEL Lab.

In light of Plaintiff's then-recent developments, Plaintiff thought it necessary, based on his prior experiences with Stanford University, to obtain certain assurances from Duke covering his work and the equipment that would be used in furtherance thereof.[1] Accordingly, Plaintiff and Defendant

1. Prior to coming to Duke University, Plaintiff was a professor and researcher at Stanford University.

allegedly entered into a Research Agreement that detailed the terms upon which Plaintiff would transfer to the University. According to Plaintiff's First Amended and Supplemental Complaint, the Research Agreement provided for the following arrangements: that Plaintiff would become a tenured faculty member of the Department of Physics, as outlined in the Duke University Faculty Handbook, that Plaintiff would locate his research and patented equipment in the FEL Lab constructed by Duke, that Plaintiff would assist the University in obtaining research grants and serve as Principal Investigator of said grants, that Plaintiff would be the Director of the FEL Lab, and that Plaintiff would be permitted to pursue research of interest to him using the laboratory's equipment and facilities. (Pl.'s First Am. & Supplemental Compl. ¶ 14.)

At some point following Plaintiff's arrival at Duke, Defendant and North Carolina Central University ("NCCU") entered into a subcontract with respect to what has been termed by Defendant as "the NCCU test stand gun" ("test gun"). Under the subcontract, Defendant was to assist NCCU in performing its research of the test gun, a gun that was closely "patterned on the microwave gun of the highly successful MKIII FEL." (Ex. A, Attach. 4; Ex. A, App. A, p. 2.) The test gun was assembled and constructed pursuant to the AFOSR-0062K Contract ("AFOSR Contract"), a contract that was awarded to NCCU by the Government. (Def.'s Ex. A, Attach. 1.) The AFOSR Contract's stated purpose was to "[d]evelop and study a microwave driven electron gun suitable for experiments to generate high frequency electromagnetic radiation." (*Id.* at 2.) The AFOSR Contract listed NCCU as the Contractor, listed Dr. Charles

Ronald Jones, an NCCU professor, as the Principal Investigator, and listed the test gun as an asset of NCCU. (Def.'s Ex. A, Attach. 3, p. 193.) The AFOSR Contract also provided for reimbursement for the work performed under the subcontract between Defendant and NCCU, so long as the costs of the subcontract did not exceed $45,117. (Ex. A, Attach. 1, p. 8.)

As to the respective responsibilities under the subcontract, Dr. Jones served as Principal Investigator and Dr. Stephen Benson, a professor at Duke, served as Senior Investigator. Pursuant to the subcontract, the test gun would be assembled and installed in the Physics Building on Defendant's campus to take advantage of the sophisticated fabrication techniques available through Defendant's shop facilities. (Ex. A ¶ 7.) The Physics Building at Duke was also considered to be an ideal location for the construction of the test gun because Defendant had an already established Radiation Safety Committee. (*See id.*)

Following the construction of the test gun, NCCU was awarded Grant No. DAAH04-93-G-0230 from the Army Research Office. (Ex. A, Attach. 5, p. 1.) This grant was entitled "Commissioning and Characterization of a Microwave Electron Gun." (*Id.*) In connection with the grant, Defendant submitted a research proposal to NCCU, proposing to "participate in the commissioning and characterization of the NCCU electron gun." (*Id.* at App. A, pp. 1-2.) Plaintiff endorsed the proposal submitted by Defendant, named himself as Principal Investigator, and signed the proposal on behalf of Defendant. (*Id.* at 1). NCCU accepted this proposal, and, on or about February 23, 1994, NCCU and Defendant entered into a second subcontract

based upon the proposal. (Ex. A, Attach. 7.) As to the responsibilities under the second contract, Dr. Jones served as Principal Investigator and Plaintiff served as the Senior Investigator.

Also with Plaintiff's assistance, the University received a federal research grant from the Office of Naval Research (the "ONR grant"). (Pl.'s First Am. & Supplemental Compl. ¶ 21.) Under the terms of the ONR grant, Plaintiff was to be the Principal Investigator for the research conducted by the University. (*Id.* at ¶ 22.) The agreement further provided that Plaintiff would have the authority to direct the research and expenditure of grant funds in accordance with the terms and conditions of the grant proposal. (*See id.*) Despite the terms set forth in the proposal, Plaintiff claims that Duke University revised the plans for construction of the FEL Lab in order to accommodate the research interests of other professors in the field of nuclear physics. (*Id.* at ¶ 32.) Plaintiff objected to the changed plans on scientific grounds and because he considered the changed plans to be an improper diversion of federal research funds. (*Id.* at ¶ 40.) According to Plaintiff, as a result of his objections, Defendant conspired to take control of the FEL Lab and his patented technology. (*Id.* at ¶ 42.) Plaintiff further claims that when he objected to the changed plans, members of the University faculty conceived of a plan to remove Plaintiff from his position of authority by engaging in the following courses of action. First, a second Director was appointed to run the FEL Lab along with Plaintiff, thereby creating a situation wherein Plaintiff's objections to changes within the Lab could be neutralized by the second Director. (*Id.* at ¶ 43). Second, Defendant created an advisory committee, composed of senior

administrators committed to the changed plans advocated by Defendant. (*Id.* at ¶ 44.) This committee had the power to veto decisions made by Plaintiff. (*Id.*). Finally, Plaintiff alleges that after he objected to these changes in the management of the Lab, Defendant removed him from his position as Director of the Lab and petitioned the Office of Naval Research to remove Plaintiff from his position as Principal Investigator on the ONR grant. (*Id.* at ¶¶ 52-56.) Since his removal, Plaintiff claims that Defendant's officials have asserted control and authority over all aspects of the research project, including the hiring and firing of personnel, the procurement of equipment and supplies, and other decisions that were within the responsibility of the Principal Investigator. (*Id.* at ¶ 54.) Shortly upon being removed from his position, and because Plaintiff objected to the manner in which the research program was being executed, Plaintiff submitted his resignation to the University. (*Id.* at ¶ 60.). Although Plaintiff's resignation became effective as of August 31, 1998, Plaintiff contends that Defendant continued to make use of the FEL equipment even after his departure. Moreover, although Plaintiff concedes that the overwhelming majority of Defendant's uses of the patented devices were for academic or experimental purposes, Plaintiff alleges that Defendant has damaged him with respect to the patented devices by depriving him "of his rights and property." (*Id.* at ¶ 57; Def.'s Ex. 4, at 173-91, Dep. of John M.J. Madey.) Plaintiff also notes that some of the research was funded by private foundations and that Defendant submitted proposals to private sources to obtain additional funding for the research program. To the extent that this occurred, Plaintiff alleges that some of the research conducted by Defendant was commercial in nature (Def.'s Ex. 4, at 173-91, Dep. of John M.J. Madey.)

As a result of all of the alleged foregoing events, Plaintiff filed the instant action, claiming infringement of the two patents (Counts I and II), conversion of property and misappropriation of business opportunities (Count III), violation of 29 U.S.C. §§ 621-634 (Count IV), violation of Plaintiff's civil rights as protected under 42 U.S.C. § 1983 (Count V), constructive fraud (Count VI), and breach of contract (Count VII). Defendant then moved to dismiss Plaintiff's Complaint, pursuant to Rules 9(b), 12(b)(1), 12(b)(6), and 12(h)(3) of the Federal Rules of Civil Procedure. Defendant's Motion to Dismiss was granted with respect to Counts IV and V; however, said motion was denied with respect to Plaintiff's other claims. Defendant has most recently filed the following motions in response to Plaintiff's remaining claims: (1) a Motion for Partial Summary Judgment of Non-Infringement of the '103 and '994 Patents Based on Government License ("Patent Motion"); (2) a Motion for Partial Summary Judgment of Non-Infringement of the '103 Patent with Respect to the NCCU Test Stand Gun ("Test Stand Gun Motion"); and a Motion for Partial Summary judgment on the State Law Claims ("State Law Motion"). Given Defendant's motions, the Court next turns to the standard of review for summary judgment claims.

II. DISCUSSION

A. Standard of Review

Summary Judgment is appropriate when "there is no genuine issue of material fact . . . and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

Material facts are those "that might affect the outcome of the suit under the governing law . . . ." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202, 211 (1986). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

In making a determination on a summary judgment motion, the Court views the evidence in the light most favorable to the nonmoving party, according that party the benefit of all reasonable inferences. *See Bailey v. Blue Cross & Blue Shield of Va.*, 67 F.3d 53, 56 (4th Cir. 1995), *cert. denied*, 516 U.S. 1159, 116 S. Ct. 1043, 134 L. Ed. 2d 190 (1996). However, mere allegations and denials are insufficient to establish a genuine issue of material fact. *See Anderson*, 477 U.S. at 248, 106 S. Ct. at 2510. Indeed, judges are not " 'required to submit a question to a jury merely because some evidence has been introduced by the party having the burden of proof, unless the evidence be of such a character that it would warrant the jury in finding a verdict in favor of that party.' " *Id.* at 251, 106 S. Ct. at 2511 (quoting *Schuylkill & Dauphin Improvement Co. v. Munson*, 81 U.S. (14 Wall.) 442, 448, 20 L. Ed. 867, 872 (1987)). Therefore, a motion for summary judgment may be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265, 273 (1986). On the other hand, a motion for summary judgment should not be granted " 'unless the entire record shows a right to judgment with such clarity as to leave no room for controversy and

establishes affirmatively that the adverse party cannot prevail under any circumstances.' " *Campbell v. Hewitt, Coleman & Assocs., Inc.*, 21 F.3d 52, 55 (4th Cir. 1994) (quoting *Phoenix Sav. & Loan, Inc. v. Aetna Cas. & Sur. Co.*, 381 F.2d 245, 249 (4th Cir. 1967)). In light of this standard for summary judgment, each of Defendant's motions for partial summary judgment is next addressed in turn.

B. Patent Motion

Plaintiff Madey first alleges that Defendant infringed his '103 Patent and his '994 Patent, respectively, by manufacturing and using microwave guns in its FEL Lab, and by using the "Mark III FEL" in the FEL Lab. Defendant has moved for partial summary judgment as to both of Plaintiff's claims of patent infringement, asserting that the activity about which Plaintiff complains constitutes "non-commercial, academic research," that is exempted by the experimental use exception from infringement liability. (Def.'s Mot. for Partial Summ. J. of Non-Infringement of the '103 & '994 Patents Based on Government License, at 8.) Defendant also contends that, to the extent that "essentially all" of its research, with respect to both patents, was authorized by the Government, conducted for the Government, or funded by the Government, said research was covered by government license and, accordingly, not subject to infringement liability. (*Id.* at 3.) In light of Defendant's assertions, the Court first turns to the experimental use exception and its applicability to the case at bar.

Appendix B

Although the "basic law of patents establishes that unauthorized use of a patented product or process constitutes infringement," for well over a century, United States "patent jurisprudence has paid homage to . . . an exception from infringement liability for . . . unauthorized uses of patented inventions[,]" where the uses were solely for research, academic, or experimental purposes. *Deuterium Core. v. United States*, 19 Cl. Ct. 624, 630 (1994); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 17 (2001); *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000). As expressed by Justice Story in *Whittemore v. Cutter*, the case in which the experimental use doctrine originated, the underlying rationale for exempting such uses from liability is that "it could never have been the intention of the legislature to punish a man, who constructed a . . . [patented device] merely for philosophical experiments. . . ." 29 F. Cas. at 1121. Although the scope of the defense has recently been the issue of much debate, to date, the experimental use defense remains viable and may be asserted in those cases in which the allegedly infringing use of the patent is made for experimental, non-profit purposes only. *See, e.g., Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (explaining that the experimental use exception is a valid defense, but that it should not be construed "so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes"); *Deuterium*, 19 Cl. Ct. at 630 (instructing that an experimental use of a patented device does not constitute patent

infringement); *Giese v. Pierce Chemical Co.*, 29 F. Supp. 2d 33 (D. Mass. 1998) (same); Julie Cohen, *Patent Scope & Innovation in the Software Industry*, 89 Cal. L. Rev. 1, 29 (2001) ("It has been settled law that purely experimental uses were noninfringing."). Given this standard, for Plaintiff to overcome his burden of establishing actionable infringement in this case, he must establish that Defendant has not used the equipment at issue "solely for an experimental or other non-profit purpose." 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000). More specifically, Plaintiff must sufficiently establish that Defendant's use of the patent had "definite, cognizable, and not insubstantial commercial purposes." *Roche Products v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856, 863 (1984) (explaining that the experimental use exception is truly narrow and that it bans all activities that are grounded on a *profit or commercial motive*) (superseded on other grounds by 35 U.S.C. § 271(e) (1994)); *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,390) ("[T]he making [of an invention] with an intent to use for profit, and not for the mere purpose of philosophical experiment [is actionable.] In other words, . . . the making must be with an intent to infringe the patent right, and deprive the owner of the lawful rewards of his discovery [to be actionable as patent infringement.]").

In this case, Plaintiff generally contends that Defendant's research in the FEL Lab was undertaken with commercial intent, thus disqualifying Defendant from the exception's protection. First, Plaintiff relies on *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051, 98 S. Ct. 903, 54 L. Ed. 2d 804 (1978), in support of this

contention. In *Pitcairn*, the patent covered rotor structures and control systems on helicopters that the plaintiff had made for the military. *See id.* at 1110-11. The Government used the patented devices on its helicopters and then claimed that its use of the patented invention was necessary to test the helicopters for "lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors." *Id.* at 1125. Despite the Government's contention that its uses were only experimental in nature, the court held the experimental use exception not to apply. *See id.* at 1126. According to the court, the uses made by the Government were intended uses of the infringing patent to the extent that they were "in keeping with the legitimate business of the using agency[.]" *Id.* at 1125-26. In sum, because the helicopters employing the patented devices were not built solely for experimental purposes, but also for the purpose of benefitting the Government in its legitimate business, the exception did not apply. *See id.*

Based on the logic in *Pitcairn*, Plaintiff points to Defendant's Policy on Inventions, Patents, and Technology Transfer to argue that, because Defendant is "in the business" of "obtaining grants and developing possible commercial applications for the fruits of its 'academic research,'" the experimental use exception does not apply to the facts in this case. Despite Plaintiff's argument, the Preamble and Objectives of the Policy on which he relies note in pertinent part:

> Duke University is *dedicated to teaching, research, and the expansion of knowledge.* Although the University *does not undertake research or*

> *developmental work principally for the purpose of developing patents and commercial applications*, patentable inventions sometimes result from the research activities carried out wholly or in part with University funds and facilities. It is the policy of the University to assure the utilization of such inventions for the common good and, where necessary, to pursue patents and licenses to encourage their development and marketing.
>
> Duke University has established the following policies and procedures with respect to inventions, patents and technology transfer in order to:
>
> A. Promote the University's *academic policy of encouraging scientific research and scholarship*. . . .

Given this specific language, the Policy does not indicate, as Plaintiff suggests, that Defendant is "in the business" of patenting and developing devices for *commercial purposes*. Instead, it suggests, to the contrary, that Defendant's primary purpose is to teach, research, and expand knowledge, and to not engage in patent development for the purpose of commercial benefit. Therefore, Plaintiff "has failed to produce contradictory evidence on [the matter of commercial intent] sufficient to survive summary judgment." *Planmatics, Inc. v. Showers*, 137 F. Supp. 2d 616, 628 (D. Md. 2001). Plaintiff's mere speculation that Defendant intends, in this case, to stray from its general policy of using patents for academic and educational purposes is insufficient to create a genuine issue of material fact. *See* Fed. R. Civ. P. 56(e); *Anderson*, 477 U.S. at 249, 106 S. Ct. at 2510 (explaining

that "a plaintiff [can not] rest on his allegations of [commercial intent when asserting a patent infringement claim] to get to a jury without any significant probative evidence tending to support the complaint") (quotations and internal quotation marks omitted); *Planmatics*, 137 F. Supp. 2d at 628 (instructing that "[a] party may not create an issue of fact through bald assertions, unsupported contentions, and conclusory statements").

Plaintiff next asserts, in support of his contention that Defendant used the patented devices with commercial intent, that Defendant receives funding from both the Government and from private foundations to cover the expenses of its research program. (Pl.'s Mem. of Law in Opp'n to Duke University's Mots. for Summ. J., at 6.) Despite Plaintiff's reliance on the sources of Defendant's funding, however, the fact that Defendant, as a non-profit institution, has obtained funding from extrinsic sources to fund the program's expenditures does not suggest improper, non-experimental use of the patent, financial gain, or commercial intent, particularly in light of the fact that Defendant has asserted and presented evidence that all of its uses of the devices covered by the '103 and '994 Patents have been in furtherance of its educational purpose or for experimentation only. *See Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935) (concluding that the experimental use exception applies when a university uses a patented device in furtherance of its educational purpose), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1935); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. Pat. Off. Soc'y 617, 633 (1985) (noting that, in light of *Ruth*, "[f]ew would deny the experimental use exception for

research on patented technology performed at a university in furtherance of its educational function"). Without more concrete evidence to rebut Defendant's stated purpose with respect to its research in the FEL Lab, Plaintiff has failed to meet its burden of establishing patent infringement by a preponderance of the evidence. *See, e.g., Afande v. National Lutheran Home for the Aged*, 868 F. Supp. 795, 802 (D. Md. 1994) (explaining that "neither speculative assertions, possibilities of factual disputes, nor a scintilla of evidence in support [of a plaintiff's] position will suffice" to withstand summary judgment) (citations omitted). Specifically, Plaintiff's unsubstantiated allegations of commercial intent, based simply upon the method by which Defendant funds its experimental research, are not sufficient to survive summary judgment. *See Planmatics*, 137 F. Supp. 2d at 627.

Plaintiff next asserts that the experimental use exception does not apply to the case at bar because Defendant claimed "a proprietary interest in the details of its work at the FEL Lab during discovery in this case." (Pl.'s Mem. of Law in Opp'n to Duke University's Mots. for Summ. J., at 6-7.) This type of assertion, from which the Court would have to draw "leaping inferences", is not enough to withstand summary judgment. *Miller v. Mercy Hosp., Inc.*, 720 F.2d 356, 363 (4th Cir. 1983) (noting that "leaps of inference [cannot] be made under the legal constraints imposed by applicable proof burdens and the requirements of demonstrable rationality in the fact-finding process"), *cert. denied*, 470 U.S. 1083, 105 S. Ct. 1841, 85 L. Ed. 2d 141 (1985); *McClamb v. Rubin*, 932 F. Supp. 706, 712 (M.D.N.C. 1996) (explaining that a plaintiff cannot survive summary judgment through mere speculation or the building of one inference upon another) (citations omitted). Specifically, even assuming that

Plaintiff's unsupported allegation is correct, the Court would have to infer from the fact that Defendant has claimed ownership in some of its research that it intends to take commercial advantage thereof. Such an inference cannot reasonably be drawn at this point, in light of Defendant's prior uses of the patented devices, which, without a contrary showing by Plaintiff, have all been experimental or educational in nature.

For all of the foregoing reasons, the Court concludes that Plaintiff's broad assertions and mere speculation as to Defendant's intent to commercially benefit from the devices covered by the '994 and the '103 Patents fail to create a genuine issue of material fact. *See Afande*, 868 F. Supp. at 802. As the Court has previously mentioned, judges are not "'required to submit a question to a jury merely because some evidence has been introduced by the party having the burden of proof, unless the evidence be of such a character that it would warrant the jury in finding a verdict in favor of that party.'" *Anderson*, 477 U.S. at 251, 106 S. Ct. at 2511 (quoting *Schuylkill & Dauphin Improvement Co. v. Munson*, 81 U.S. (14 Wall.) at 448, 20 L. Ed. at 872. Because the evidence presented in this case is not of such a character "that it would warrant the jury in finding a verdict" in Plaintiff's favor, Defendant's Patent Motion is GRANTED.[2]

2. The Court notes at this point that Plaintiff has also presented certain supplemental evidence in support of his infringement claim, on which he did not rely in his response brief. Specifically, Plaintiff has presented testimony about a fee that Defendant has established for industrial users wishing to use the FEL Lab's resources. (Def.'s Ex. 4, at 173-91.). Although this fee has been in existence for some time, it has not yet been applied. In fact, all users to date,

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even by Plaintiff's own acknowledgment, have been faculty members of Duke, other academics, or non-industrial users seeking to pursue experimental interests. (*See id.*) Therefore, Plaintiff's mere speculation and general averment that such a fee establishes commercial intent, in light of all of the other non-speculative evidence suggesting the contrary, are insufficient to sustain Plaintiff's claim of infringement. *See, e.g., Planmatics*, 137 F. Supp. 2d at 628 ("[U]nsubstantiated allegations . . . are not sufficient to survive summary judgment. A party may not create an issue of fact through bald assertions, unsupported contentions, and conclusory statements.") (citations omitted).

The Court also notes that Plaintiff has attested that Defendant both posted information on its website and issued public announcements on five research programs that are to be carried out at Defendant's new technology center, the Fitzpatrick Center for Photonics & Communication Systems. (Supplemental Aff. of John M.J. Madey ¶ 14.). According to Plaintiff, two of these research programs "involve" FEL technology. (*Id.*) Plaintiff further claims that Defendant's website indicates that Defendant will engage in corporate partnerships in furtherance of its research goals. (*Id.* ¶ 15.) Plaintiff then concludes that "[i]t is evident from these materials that research activity is currently underway and that greater use of the patented equipment is planned." However, despite Plaintiff's assertions and conclusions with respect to these informational sources, the text to which Plaintiff points in support of his claim is too broad and too vague to establish that Defendant intends to commercially benefit from the *FEL technology* specifically, which composes only a portion of the technology to be used by the center for its programs. Moreover, even assuming that the language to which Plaintiff points does apply to the use of FEL technology in the new center, this language refers to the development and licensing of *new* technology, and not of equipment or patents currently in existence. Therefore, Plaintiff has
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To the extent that the Court has granted Defendant's Patent Motion, Defendant's alternative argument that "essentially all" of its uses with respect to the '994 and '103 Patents were covered by Government license is moot. The Court does note, however, as it did previously when ruling upon Defendant's Motion to Dismiss, that all uses that have been made of the patented devices that are covered by such a license are not subject to infringement liability.[3]

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not presented enough evidence from which a reasonable jury can conclude that the objectives of the center with respect to Plaintiff's FEL technology are improper, and Plaintiff's mere forecast of the same is not legally competent evidence sufficient to rebut Defendant's evidence of non-commercial intent. *Planmatics*, 137 F. Supp. 2d at 628 (explaining that a plaintiff must produce "legally competent evidence from [which] a jury could reasonably" conclude in the plaintiff's favor); *Miller*, 121 F. Supp. 2d at 837 (same).

3. Such a conclusion is supported by the Bayh-Dole Act, 35 U.S.C. §§ 200-212, which establishes that the Government has an irrevocable paid up license to have patents practiced on its behalf, where it has funded the development of such patents. Specifically, the Act provides:

> (c) Each funding agreement [between the Government and] a . . . nonprofit organization shall contain appropriate provisions to effectuate the following:
>
> . . .
>
> (4) With respect to any invention in which the contractor elects rights [to the invention], the Federal Agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced

(Cont'd)

Appendix B

C. Test Stand Gun Motion

Defendant next moves for partial summary judgment on Plaintiff's claim that both Defendant's manufacture of the test gun and its use of that gun since June of 1997 (hereinafter, the period following June of 1997 will be referred to as "the relevant date") infringe the '103 Patent. According to Defendant, the manufacture, itself, of the test gun does not give rise to a meritorious infringement claim, because the test gun was manufactured with Plaintiff's consent. As to Plaintiff's claim that Defendant's use of the test gun after the relevant date constitutes patent infringement, Defendant simply alleges that said claim is without merit, because it has not used the test gun since the relevant date. The federal patent statute helps to shed light on the merits of Defendant's motion for partial summary judgment.

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> for or on behalf of the United States any subject invention throughout the world. . . . .

35 U.S.C. § 202(c)(4). In this case, the funding agreements for the inventions created under the '994 and '103 patents expressly provide that the Government retained rights in those inventions. Therefore, in light of the Bayh-Dole Act and said funding agreements, those uses that Defendant has made with respect to the '103 and '994 Patents that have been authorized by the Government do not constitute patent infringement to the extent that such uses are protected by an irrevocable government license.

Although the parties have presented conflicting evidence as to the extent to which the patented devices have been used for a purpose consented to by the Government, because Plaintiff has failed to create a genuine issue of material fact as to whether Defendant has commercially benefitted or intends to do so with respect to the patents at issue, the uses that have been made to date with respect to both patents are, at this point, exempt from infringement liability.

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The federal patent statute provides, in pertinent part, that "whoever *without authority* makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (emphasis added). In light of this standard, the Court next turns to whether Plaintiff correctly asserts that Defendant's manufacture of the test gun constitutes actionable infringement. Unless Plaintiff can establish that Defendant's manufacture of the test gun was "without [Plaintiff's] authority," Defendant's motion with respect to the gun's manufacture must be granted. Plaintiff, however, is unable to make such a showing.

Specifically, the NCCU test stand gun was assembled and installed in the Physics Building at Duke while Plaintiff was employed at the FEL Lab. In fact, *by Plaintiff's own admission*, Plaintiff had knowledge that the NCCU test stand gun was being constructed, and even supervised the construction thereof. (Def.'s Ex. B, p. 160.) Plaintiff's authorization of the test gun's manufacture is further evidenced by the fact that following completion of the test gun, Defendant, with Plaintiff's assistance, submitted a research proposal to NCCU, proposing to assist in the commissioning and characterization of the gun. (Def.'s Ex. A, App. A, pp. 1-2.) Importantly, Plaintiff endorsed this research proposal by naming himself as Principal Investigator and by signing the proposal on Defendant's behalf. In light of the foregoing facts, Plaintiff unquestionably authorized the manufacture by Defendant of the test gun. Accordingly, Plaintiff's claim of patent infringement must fail, and Defendant's motion for partial summary judgment as to the manufacture of the test gun is GRANTED.

Defendant next moves for partial summary judgment on Plaintiff's claim that Defendant's "use and operation" of the

test gun after the relevant date infringes the '103 Patent. According to Defendant, this motion should be granted because, contrary to Plaintiff's allegations, it did not use the test gun after the relevant date. In support of its motion, Defendant relies on the affidavit of Dr. Charles Ronald Jones, a professor at NCCU.

In his affidavit, Dr. Jones attests that he is the only person authorized by the Duke Radiation Safety Committee to operate the NCCU test stand gun. (Def.'s Ex. A ¶ 14.) In fact, Dr. Jones must be physically present for the NCCU test stand gun to be turned on. (*See id.*) To ensure that no one else uses the device without Dr. Jones' authorization, there is a key switch to the NCCU test stand gun to which Dr. Jones has sole access. (*See id.*) Considering this fact, Dr. Jones would have direct knowledge if Defendant's employees used or operated the NCCU test stand gun for any reason after the relevant date. Yet, according to Dr. Jones, he "is unaware of any Duke faculty member or employee [who has used or operated] the NCCU test stand gun at any time since at least June of 1997," the date on which Plaintiff alleges Defendant's infringement of the '103 Patent began. (*Id.* ¶ 15.) To the extent that Dr. Jones, the sole holder of the key to the test gun, has stated that Defendant's employees and faculty members have not made use of the test gun since the relevant date, no genuine issue of material fact exists as to this point. This is true to the extent that Plaintiff's bald allegations and mere speculation in contradiction of Dr. Jones' testimony are insufficient to withstand summary judgment.[4]

4. The Court also notes at this point that Plaintiff asserts that graduate students at the University have made use of the gun for educational purposes since the relevant date. (Pl.'s Mem. of Law

(Cont'd)

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Plaintiff next argues that Defendant is liable for patent infringement to the extent that *NCCU* professor Dr. Jones has used the test gun since the relevant date. In support of this argument, Plaintiff alleges that Dr. Jones is an authorized agent of the University, and that Dr. Jones has co-authored publications with members of the Duke faculty. (Pl.'s Mem. of Law in Opp'n to Duke University's Mots. for Summ. J., at 2-3.) However, Plaintiff's assertions of agency and of publication by Defendant's faculty members after the relevant date are directly refuted by a second affidavit that was submitted by Dr. Jones. In this second affidavit, Dr. Jones attested that he is not and has never been the authorized agent of Defendant, that Defendant has no control over the operation of the test gun, that the gun is not operated under the control of or for the benefit of Duke, and that all of his publications that were co-authored by Duke faculty members either involved research conducted prior to the relevant date, or did not, in any manner, involve use or operation of the test gun. (Ex. 1, Jones Aff. ¶¶ 2-6.) Not only does the affidavit of Dr. Jones establish that he was not an agent of Duke University, but the subcontract entered into by the parties with respect to the test gun also supports such a conclusion. Specifically, the subcontract expressly provides that "[Duke's] relationship to NCCU under [the] agreement [was] that of an independent Contractor and not an agent, joint venturer or partner of NCCU,"

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in Opp'n to Duke University's Mots. for Summ. J., at 2-3.) Even assuming Plaintiff's version of these facts to be true, the experimental use exception would foreclose Plaintiff's claim of patent infringement. Moreover, Dr. Jones testified, contrary to Plaintiff's assertions, that no student from the University has made use of the test gun since June of 1997. (Ex. 1, Jones Aff. ¶¶ 2-6.) Once again, Plaintiff's general averments, without supporting evidence, contradicting this testimony do not suffice to create a genuine issue of material fact.

suggesting that agency liability does not exist, on either side. In light of these facts, Plaintiff's attempt to hold Defendant accountable for patent infringement because of Dr. Jones' use of the test gun is fatally flawed. For the foregoing reasons, Defendant's Motion for Partial Summary Judgment of Non-Infringement with Respect to the NCCU Test Stand Gun is GRANTED in all respects.[5]

The Court notes at this point that the parties have presented a substantial amount of evidence with respect to the state law claims at issue in this case, in response to and in support of Defendant's State Law Motion.[6] Although the Court has reviewed the aforementioned evidence, the Court will, in its discretion, decline to exercise supplemental jurisdiction over

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5. Although Plaintiff contends in his First Amended and Supplemental Complaint that Defendant infringed his '103 Patent by manufacturing and *previously* using the test gun after the relevant date, in Plaintiff's Supplemental Affidavit, he seemingly suggests that Defendant plans to infringe his '103 Patent *in the future* to the extent that it plans to use the test gun in its new research center. However, for the same reasons that the Court has concluded that the information in the alleged website is insufficient to withstand summary judgment as to the Patent Motion, the Court makes the same finding with respect to the Test Stand Gun Motion. Plaintiff's claim is too speculative at this point to create a genuine issue of material fact.

6. Specifically, Defendant has moved for summary judgment in its State Law Motion on Plaintiff's state law claims of conversion of property, misappropriation of business opportunities, constructive fraud, and breach of contract. To address these claims, both parties have presented numerous documents as to the proper owner of the patented equipment currently housed at Duke. The issue of ownership, however, was not essential to the Court's determination of the patent infringement issues addressed herein.

said claims. Specifically, to the extent that summary judgment has been granted on all of Plaintiff's federal law claims, Plaintiff's state law claims are dismissed without prejudice.

IV. CONCLUSION

For the foregoing reasons, Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '103 and '994 Patents Based on Government License and Defendant's Motion for Partial Summary Judgment of Non-Infringement with Respect to the NCCU Test Stand Gun are GRANTED. Furthermore, because the Court will grant Defendant's motions for partial summary judgment on Plaintiff's federal claims, the Court will not consider Defendant's motion for partial summary judgment as to Plaintiff's remaining state law claims. Instead, pursuant to 28 U.S.C. § 1367(c)(3), the Court will decline to exercise supplemental jurisdiction over Plaintiff's state law claims and dismiss said claims without prejudice.

This, the 15 day of June, 2001.

s/ James A. Beaty
United States District Judge

Appendix B

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

1:97CV01170

JOHN M. J. MADEY,

Plaintiff,

v.

DUKE UNIVERSITY,

Defendant.

ORDER AND JUDGMENT

BEATY, District Judge.

For the reasons enumerated in the MEMORANDUM OPINION filed contemporaneously herewith,

It is ORDERED, ADJUDGED, AND DECREED that Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '103 and '994 Patents Based on Government License [Document # 65] and Defendant's Motion for Partial Summary Judgment of Non-Infringement with Respect to the NCCU Test Stand Gun [Document # 60] are GRANTED. Furthermore, because the Court grants Defendant's motions for partial summary judgment as to Plaintiff's federal claims, the Court will not consider Defendant's motion for partial summary judgment as to

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Plaintiff's remaining state law claims [Document # 63]. Instead, pursuant to 28 U.S.C. § 1367(c)(3), the Court declines to exercise supplemental jurisdiction over Plaintiff's state law claims, and said claims are dismissed without prejudice.

This, the 15 day of June, 2001.

s/ James A. Beaty
United States District Judge

APPENDIX C — MEMORANDUM OPINION AND ORDER AND JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA DATED AND FILED DECEMBER 1, 1999

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

1:97CV1170

JOHN M. J. MADEY,

Plaintiff,

v.

DUKE UNIVERSITY, CHARLES E. PUTMAN, JOHN STROHBEHN, WILLIAM H. CHAFE, BERNDT MUELLER, BOBBY GUENTHER, and LAWRENCE EVANS

Defendants.

MEMORANDUM OPINION

BEATY, District Judge.

I. INTRODUCTION

This matter is before the Court on the separate motions of Defendant Duke University [Document #30] and Duke Individual Defendants [Document #31], in which both parties move to dismiss John M. J. Madey's First Amended

and Supplemental Complaint [Document # 28] pursuant to Rules 8, 9(b), 12(b)(1), 12(b)(6) and 12(h)(3) of the Federal Rules of Civil Procedure.[1] Plaintiff's Complaint includes claims for infringement of two patents (Counts I and II); conversion of property and misappropriation of business opportunities (Count III); violation of 29 U.S.C. §§ 621-634, the Age Discrimination in Employment Act ("the ADEA") (Count IV); violation of Plaintiff's civil rights as protected under 42 U.S.C. § 1983 (Count V); constructive fraud (Count VI); and breach of contract (Count VII).

II. FACTS

Plaintiff came to Duke University in 1989 as a tenured professor to assist the University in establishing the Free Electron Laser Laboratory ("FEL Lab") and research program. Before coming to Duke, Plaintiff secured United States Patent No. 4,641,103 for the microwave electron guns now used in the FEL Lab at Duke University (" '103 patent"). Plaintiff also developed the Mark III, a Free Electron Laser that he constructed at Stanford University using federal research funds, his own funds, and assistance from Stanford. On July 14, 1992, while serving as a tenured professor at Duke, Plaintiff and E.B. Szarmes secured U.S. Patent No. 5,130,994 (the "994 patent") for the "Free Electron Laser Oscillator for Simultaneous Narrow Spectral Resolution and Fast Time Resolution Spectroscopy." Plaintiff claims that he is now the sole owner of this patent. When Plaintiff left his position at Stanford, Stanford released all ownership

1. The individual Defendants in this action are Charles E. Putman, John Strohbehn, William H. Chafe, Berndt Mueller, Bobby Guenther and Lawrence Evans.

interests in the Mark III and other FEL equipment, leaving Plaintiff as the sole owner subject to the rights of the United States government. Plaintiff claims that as part of the Research Agreement between himself and Duke University, Duke agreed that Plaintiff would retain use and control of his patents and all related equipment.

According to Plaintiff's First Amended and Supplemental Complaint, the Research Agreement between Plaintiff and Defendant Duke University provided that Plaintiff would become a tenured faculty member of the Department of Physics as outlined in the Duke University Faculty Handbook, that Plaintiff would locate his research in the FEL Lab constructed by Duke to house Plaintiff's patented equipment, that Plaintiff would assist the University in obtaining research grants and serve as Principal Investigator of said grants, that Plaintiff would be Director of the FEL Lab, and that Plaintiff would be permitted to pursue research of interest to him using the laboratory's equipment and facilities. Subsequent to Plaintiff's arrival at Duke, the University received a federal research grant from the Office of Naval Research (the "ONR grant"). Under the terms of the ONR grant, Plaintiff was to be the Principal Investigator for the research conducted by the University. He would have the authority to direct the research and expenditure of grant funds in accordance with the terms and conditions of the grant proposal upon which the ONR grant was awarded.

Plaintiff claims that Duke University and the Individual Defendants revised the plans for construction of the FEL Lab facilities in order to accommodate the research interests of other professors in the field of nuclear physics. Plaintiff

objected to the changed plans on scientific grounds and because he considered the changed plans to be an improper diversion of federal research funds. Plaintiff claims that as a result of his objections, Defendant Duke University and Duke Individual Defendants conspired to take control of the FEL Lab and Plaintiff's patented technology. As explained *supra*, Plaintiff alleges that the Defendant revised the plans for construction of the FEL Lab facilities in order to pursue the research of other professors in the Physics Department. Plaintiff claims that when he objected to the changed plans, members of the University faculty conceived of a plan to remove Plaintiff from his position of authority. First, a second Director was appointed to run the lab along with Plaintiff, thereby creating a situation wherein Plaintiff's objections to changes within the Lab could be neutralized by the second Director. (Plain. First Amend. Supp. Comp. at ¶ 43.) Second, Plaintiff claims that Defendant University created an advisory committee, composed of senior administrators committed to the changed plans advocated by Defendant. This committee would have the power to veto decisions made by Plaintiff. (*Id.* at ¶ 44.) Finally, Plaintiff alleged that after he objected to these changes in the management of the Lab, Defendant removed him from his position as Director of the Lab and petitioned the Office of Naval Research to remove Plaintiff from his position as Principal Investigator of the ONR grant. (*Id.* at ¶ 52-26.) Plaintiff claims that in addition Defendants also excluded him from the use of the laboratory and his FEL equipment. (*Id.* at ¶ 52-26.) Plaintiff also claims that Defendants continue to use his FEL equipment. As a result of these alleged events, Plaintiff has brought claims for infringement of the two patents (Counts I and II), conversion of property and misappropriation of business opportunities

(Count III), violation of 29 U.S.C. §§ 621-634 (Count IV), violation of Plaintiff's civil rights as protected under 42 U.S.C. § 1983 (Count V), constructive fraud (Count VI), and breach of contract (Count VII). Plaintiff has brought the claims of patent infringement, conversion, misappropriation of business opportunities, violation of civil rights under § 1983, and constructive fraud against both Duke University and the Individual Duke Defendants. The claims for age discrimination and breach of contract are only alleged against Duke University. Defendants Duke University and the Individual Defendants have moved to dismiss Plaintiff's complaint pursuant to Rules 9(b), 12(b)(1), 12(b)(6), and 12(h)(3) of the Federal Rules of Civil Procedure. The Individual Defendants also move to dismiss Plaintiff's complaint pursuant to Rule 8 of the Federal Rules of Civil Procedure.

III. DISCUSSION

Plaintiff and the Individual Defendants have filed motions between themselves separate and apart from those motions filed between Plaintiff and Defendant Duke University. However, the Individual Defendants incorporate the pleadings of Defendant Duke University into their defense. In most instances, the claims and defenses of the pleadings between the Individual Defendants and Plaintiff are identical to the claims and defenses of the pleadings between Defendant Duke University and Plaintiff. This Court finds, however, that because Plaintiff's allegations against University faculty Putman, Strohbehn, Chafe, Mueller, Guenther and Evans are based upon actions allegedly taken by them in their individual capacities, a separate discussion

is necessary with respect to those defendants. Therefore, the Court will first discuss Individual Defendants' Motion to Dismiss Plaintiff's First Amended and Supplemental Complaint.

A. Individual Defendants' Motion to Dismiss Pursuant to Fed.R.Civ.P 8

Plaintiff has brought the claims of patent infringement, conversion, misappropriation of business opportunities, violation of civil rights under § 1983, and constructive fraud against the Individual Duke Defendants. The Individual Defendants have moved to dismiss Plaintiff's claims pursuant to Rules 8, 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

Rule 8(a)(2) requires that a pleading contain "(2) a short and plain statement of the claim showing that the pleader is entitled to relief. . . ." A leading case on federal pleading requirements under Rule 8 is *Conley v. Gibson*, 355 U.S. 41, 78 S.Ct. 99 (1957). In *Conley*, the Supreme Court held that Rule 8 simply requires "notice pleading," and "do[es] not require a claimant to set out in detail the facts upon which he bases his claim." *Id.*, 355 U.S. at 47, 78 S.Ct. at 102. Instead, the Court stated that Rule 8 requires " 'a short and plain statement of the claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Id.* According to the Court, this approach is a rejection of the notion that "pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and [an acceptance of] the principle that the purpose of pleading is to facilitate a proper decision on the merits." *Id.*, 355 U.S. at 48, 78 S.Ct. at 103.

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Although the Supreme Court's liberal approach to Rule 8 review gives plaintiffs wide latitude in constructing pleadings, the case law of several of the circuits that have interpreted *Conley* suggests that the case should not be construed to eliminate the requirement that a plaintiff state some facts upon which a claim is based. The Sixth Circuit, focusing on the *Conley* Court's statement that a defendant should be informed of the "grounds upon which [a claim] rests," reasoned that the language in *Conley* implicitly suggests that the Federal Rules " 'do contemplate a statement of circumstances, occurrences, and events in support of the claim being presented.' " *McGregor v. Industrial Excess Landfill, Inc.*, 856 F.2d 39, 42 (6th Cir. 1988) (per curiam) (quoting 5 Wright & Miller, Federal Practice and Procedure § 1215 (1969)). The First Circuit, acknowledging the Supreme Court's purpose in establishing a liberal approach to Rule 8, nevertheless stated that "[c]ompeting concerns . . . speak in favor of requiring at least some level of 'particularity' or 'specificity.' " *Boston & Maine Corp. v. Town of Hampton*, 987 F.2d 855, 865 (1st Cir. 1993). As one of the court's nonexclusive list of concerns, it noted: ". . . a complaint that is too general will not 'give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests.' " *Id.* at 865. Echoing the Sixth Circuit's sentiment, the Seventh Circuit, in *Kyle v. Morton High School*, 144 F.3d 448 (7th Cir. 1998), reviewed a series of cases where that circuit dismissed pleadings because they did not adequately notify the defendants of the operative facts underlying the claims brought. *See, e.g., Panaras v. Liquid Carbonic Industries Corp.*, 74 F.3d 786, 792 (7th Cir. 1996) ("While federal notice-pleading allows for a generous reading of a complaint, in order to resist a motion to dismiss, the complaint must at

least set out facts sufficient to 'outline or adumbrate' the basis of the claim."); *McTigue v. City of Chicago*, 60 F.3d 381, 382 (7th Cir. 1995) ("The complaint, however, is deficient because it fails to include a factual basis to describe with particularity the bias that the plaintiff alleges. Although Fed. R. Civ. P. 8 does not require detailed factual pleading, a plaintiff's assertions must still direct the defendant to the factual cause of the plaintiff's alleged injury."); *Perkins v. Silverstein*, 939 F.2d 463, 467 (7th Cir. 1991) ("While plaintiffs make clear in their original complaint what their claims are, they fail to identify the grounds upon which their claims are based. This they must do, even under the liberal notice pleading of Rule 8(a)." (footnote and citation omitted.))

In the present case, Plaintiff has failed to present any set of facts that would adequately notify the Individual Defendants of the basis of the claims against them. As the Individual Defendants note in their motion to dismiss, Plaintiff barely mentions them by name, and never ascribes to them any behavior that corresponds to the claims alleged. (Ind. Def.'s Mot. Dis. First Amend. Supp. Comp. at 6.) For example, Plaintiff alleges that Defendants Mueller and Evans "developed a plan to take control of the [medical FEL] project and remove Dr. Madey from his position of authority in order to facilitate their nuclear research plans." (First Amend. Supp. Comp. at ¶ 33.) He also accuses them of signing construction plans for the FEL Lab on behalf of Duke. (*Id.* at ¶ 38.) Defendant Chafe is only mentioned by name for the purposes of showing that the Court has jurisdiction over him. (*Id.* at ¶ 3.) Plaintiff's allegations against Defendants Strohbehn and Putman are that they "ratified, condoned and affirmed" academic misconduct. (*Id.* at ¶ 134(d).) Plaintiff does not

attribute any action to Defendant Guenther, except to simply state that he was hired by Duke as an interim director of the FEL Lab. (*Id.* at ¶ 34.) However, these allegations fail to notify the Individual Defendants of the actions or circumstances behind Plaintiff's claims, and leave the Defendants unable to prepare an adequate defense to said claims. Thus, Plaintiff's complaint fails to meet even the liberal notice requirement of Rule 8 of the Federal Rules of Civil Procedure, and the Court finds it appropriate to dismiss Plaintiff's claim as to the Individual Defendants on that basis. Given the Court's finding on the issue of insufficient notification under Rule 8, it is unnecessary for the Court to consider Defendants' contention that Plaintiff's claims should be dismissed pursuant to Rule 12(b)(6) for failure to state a claim. Accordingly, for the remainder of this Memorandum Opinion, the Court will discuss Plaintiff's claims only against Defendant Duke University.

B. Count I: Patent Infringement[2]

Defendant Duke University has moved to dismiss Plaintiff's claim for infringement of the '103 patent for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure. The Court will consider these motions in turn.

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2. Plaintiff alleges infringement of two patents: the '103 patent and the '994 patent. Though both claims of patent infringement are brought against Duke University and the Individual Defendants, Duke University only moves to dismiss the claim for infringement of the '103 patent, not the '994 patent.

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1. Dismissal Pursuant to Federal Rules of Civil Procedure 12(b)(1).

For the purposes of considering whether this Court has jurisdiction to consider Plaintiff's claim of infringement of the '103 patent, it is necessary to separate the allegations of unauthorized use made by Plaintiff against Defendant into two categories: use in furtherance of the ONR grant, and use that exceeds the authorized scope of the ONR grant. Title 28 U.S.C. § 1498(a) provides in part:

> (a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation *for the Government and with the authorization or consent of the Government*, shall be construed as use or manufacture for the United States.

28 U.S.C. § 1498(a) (emphasis added).

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Title 28 U.S.C. § 1338(a) states:

> (a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trade-marks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

28 U.S.C. § 1338(a).

Thus, it is clear that if Plaintiff's claim of infringement only concerned Defendant's use of the '103 patent for the government, jurisdiction would be proper only before the Court of Claims as provided by § 1498(a). It is also clear that if Plaintiff's claim only concerned Defendant's use of the '103 patent outside the scope of the government grant (i.e. for purely private purposes), jurisdiction would be proper before any district court pursuant to § 1338(a). In the present case, however, the issue is whether the Court of Claims should have jurisdiction where Defendant alleges that both types of unauthorized use took place.

The Fourth Circuit has set out the standard of review for motions to dismiss pursuant to 12(b)(1). In *Richmond, Fredericksburg & Potomac R. Co. V. United States*, 945 F.2d 765, 768 (4th Cir. 1991), *cert denied*, 503 U.S. 984, 112 S.Ct. 1667, 118 L.Ed.2d 388 (1992), the court held that "when a Rule 12(b)(1) motion challenge is raised to the factual basis for subject matter jurisdiction, the burden of proving subject matter jurisdiction is on the plaintiff." *Richmond*, 945 F.2d

at 768. (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982)). The court relied on *Trentacosta v. Frontier Pacific Aircraft Indus.*, 813 F.2d 1553, 1558 (9th Cir. 1987), where the Ninth Circuit ruled that in determining whether jurisdiction exists, the district court is to regard allegations in the pleadings as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment. *Trentacosta*, 813 F.2d at 1558 (9th Cir. 1987). The district court should apply the standard applicable to a motion for summary judgment, under which the nonmoving party must set forth specific facts beyond the pleadings to show that a genuine issue of material fact exists. *Trentacosta*, 813 F.2d at 1559 (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 2552-53, 91 L.Ed.2d 265 (1986)). The moving party should prevail only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law. *Trentacosta*, 813 F.2d at 1558.

In Defendant's Reply Memorandum in Support of Duke University's Motion To Dismiss Counts One, Three, Four, Five, Six and Seven of Plaintiff's First Amended and Supplemental Complaint, Defendant contends that because at least a portion of Plaintiff's infringement claim is within the exclusive jurisdiction of the Court of Claims, this Court should dismiss the entire claim, including those allegations that Defendant infringed upon the patent for its own private uses. (Def.'s Reply Mem. Supp. Mot. Dis. at 1-2). Defendant cites *Temco-Vought, Inc. v. Kollsman Instrument Co.*, 372 F.2d 263, 269-70 (2d Cir. 1967), where the Second Circuit ruled that a district court's dismissal of a patent infringement claim was proper because, in addition to unauthorized uses

by the defendant government contractor for its own private purposes, there were unauthorized uses by the defendant for the government. The district court's ruling turned on the court's application of the *de minimis* doctrine. In applying the *de minimis* doctrine, the court decided that because the defendant's use of the patent for its own private purposes was very limited— consisting of advertising that did not produce sales and unsuccessful experimentation— such private use could not remove jurisdiction under § 1498 from the Court of Claims. The appellate court affirmed the district court's application of the *de minimis* doctrine as a means of dismissing the claim. *Temco-Vought, Inc.*, 372 F.2d at 269-70. Thus, where a private defendant infringes a patent both in service of the government and for its own private purposes, but the infringement for private purposes is unsuccessful or sufficiently limited, the district court may properly dismiss the entire action on jurisdictional grounds. However, on the facts before this Court, the extent of Defendant's use of the '103 patent for private purposes is unclear. Defendant claims that any unauthorized uses of the '103 patent "were not for commercial gain and were at best *de minimis*." (Def.'s Reply Mem. Supp. Mot. Dis. at 2). Plaintiff, however, alleges that since June 1997, Duke has used the '103 patent "for [its] own purposes and benefit." (First Amend. Supp. Comp. at 20, ¶ 74.) The exact nature and extent of Defendant's unauthorized use of the '103 patent is a factual question that will require determination through discovery. Since the material facts underlying the jurisdictional issue are in dispute as to the alleged nongovernmental uses of Plaintiff's patent, the Court will deny Defendant's motion to dismiss with respect to those uses. With respect to Defendant's uses of the patent under the authority of the

government research grant, the Court will grant Defendant's motion to dismiss Plaintiff's claim for patent infringement without prejudice. Therefore, consistent with this ruling, the Court will consider Defendant's motion to dismiss pursuant to Rule 12(b)(6) only as it relates to alleged uses of the patent for Defendant's own private purposes.

2. Dismissal Pursuant to Federal Rules of Civil Procedure 12 (b) (6).

With respect to a motion to dismiss for failure to state a claim upon which relief can be granted, dismissals are allowed only in very limited circumstances. *Rogers v. Jefferson-Pilot Life Ins. Co.*, 883 F.2d 324, 325 (4th Cir. 1989). Generally, a court should not dismiss a complaint for failure to state a claim "unless it appears certain that the plaintiff can prove no set of facts which would support its claim and would entitle it to relief." *Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197, 127 L. Ed. 2d 658 (1994). In making this determination, a court must view the complaint in the light most favorable to the plaintiff, accepting as true all well-pleaded factual allegations. *Randall v. United States*, 30 F.3d 518, 522 (4th Cir. 1994), *cert. denied*, 514 U.S. 1107, 131 L. Ed. 2d 849 (1995).

Defendant argues that the government's retained rights in the patent gave the government the right to authorize each of Defendant's uses of the patent. (Def.'s Mot. Dis. First Amend. Supp. Comp. at 8.) As stated earlier, the Court now reviews Defendant's 12(b)(6) motion only as it applies to Plaintiff's allegation that Defendant used the patent for

nongovernmental purposes. The fact that the government retains rights in the patented invention is not dispositive of this issue. Even with the government's retained rights, the question remains whether the government's retained rights amount to ownership such that the government could authorize Defendant's use of Plaintiff's patent for private purposes. At this point, Plaintiff has alleged that he is the sole owner of the patent and that he did not authorize its use by Defendant for Defendant's private purposes. These allegations are sufficient to state a claim of infringement and to withstand a motion to dismiss. Thus, Defendant's 12(b)(6) motion to dismiss is denied as to the infringement claim.

C. Count III: Conversion and Misappropriation of Business Opportunities

Plaintiff alleges that Defendant's continued exercise of exclusive control over the Mark III and other patented equipment constitutes conversion and misappropriation of Plaintiff's business opportunities. Defendant has moved to dismiss both allegations for failure to state a claim pursuant to 12(b)(6).

1. Conversion

As with Defendant's motion to dismiss Plaintiff's infringement claim, Defendant moves to dismiss Plaintiff's conversion claim on the basis of the authority it has received to use the patent based upon the government's retained right of use in the patent. Under North Carolina law, conversion is defined as "an unauthorized assumption and exercise of the right of ownership over goods or personal chattels

belonging to another, to the alteration of their condition or the exclusion of an owner's rights." *Peed v. Burleson's, Inc.*, 244 N.C. 437, 439; 94 S.E.2d 351, 353 (1956) (quoting 89 C.J.S. Trover & Conversion § 1.) However, as this Court has noted, "this definition clearly does not provide an independent standard for determining whether conversion occurred, for what constitutes an 'unauthorized' interference with another's ownership of goods or chattels depends upon the circumstances under which such interference arose." *Binkley v. Loughran*, 714 F.Supp. 776, 779 (M.D.N.C. 1989). In the present case, Plaintiff claims that in spite of the government's retained rights, he is the sole owner of the patented equipment in the FEL Lab, and therefore he possesses sole authority to allow the use of his patented equipment. Plaintiff argues further that even if he and the United States were joint owners of the equipment in question, the United States could not properly grant exclusive possessory rights to Defendant. Such an assignment would be in excess of the government's interest in the patent and would constitute conversion. *See Myers v. Myers*, 68 N.C. App. 177, 314 S.E.2d 809 (1984) (where a husband's use of more than his interest in a joint bank account held with his wife without accounting to his wife amounted to conversion). Additionally, the acceptance by Defendant of any rights of use that exclude Plaintiff from his ownership rights constitute conversion. *Wall v. Colvard, Inc.*, 268 N.C. 43, 48; 149 S.E.2d 559, 563 (1966) (ruling that a junior mortgagee holding mortgaged property to the exclusion of a senior mortgagee committed conversion since the junior mortgagee's action constituted a claim of title inconsistent with its true entitlement). In this case Plaintiff has alleged that Defendant "seized control of the [Free Electron Laser] Lab and the

equipment . . . and [has] excluded [Plaintiff] from all management or control of the Lab, its equipment and operations." (First Amend. Supp. Comp. at 20, ¶ 73.) The Court finds that such allegations sufficiently raise the issue of whether there has been an unauthorized exclusion of Plaintiff's rights. Plaintiff's allegations properly state a claim for conversion. Therefore, Defendant's motion to dismiss Plaintiff's conversion claim pursuant to 12(b)(6) is denied.

2. Misappropriation of Business Opportunities

Plaintiff alleges that Defendant's actions constitute a misappropriation of Plaintiff's business opportunities. Defendant argues that Plaintiff fails to state a claim for misappropriation of business opportunities on the theory that there was no fiduciary relationship between Defendant and Plaintiff that could be violated, and therefore no misappropriation. Defendant is correct in stating that a claim of misappropriation of business opportunities would require a fiduciary relationship. *See Meiselman v. Meiselman*, 309 N.C. 279, 307, 307 S.E.2d 551, 567 (1983) (ruling that a plaintiff, in order to prevail on a claim of misappropriation of corporate opportunity, must prove that a defendant breached a fiduciary duty.) Under North Carolina law, a fiduciary relationship may exist under a "variety of circumstances," and exists "in all cases where there has been a special confidence reposed in one who in equity and good conscience is bound to act in good faith and with due regard to the interests of the one reposing confidence." *Hajmm v. House of Raeford Farms*, 328 N.C. 578, 588, 403 S.E.2d 483, 489 (1991). While North Carolina courts define certain relationships, such as that between business partners,

as fiduciary relationships as a matter of law, in most situations "the question of whether a fiduciary relationship exists is more open and depends ultimately on the circumstances." *Terry v. Terry*, 302 N.C. 77, 84, 273 S.E.2d 674, 677 (1981). Defendant contends that there can be no fiduciary relationship between a professor and the university employing the professor. Defendant relies on *Speck v. North Carolina Dairy Foundation, Inc.*, 311 N.C. 679, 319 S.E.2d 139 (1984), where defendant North Carolina State University refused to share profits from a secret process with the plaintiffs, a professor and faculty assistant who developed the process. The plaintiffs in *Speck* argued that they shared a fiduciary relationship with the university that required that any profits derived from plaintiffs' invention be shared. According to the plaintiffs, the violation of this fiduciary relationship entitled plaintiffs to a constructive trust on the proceeds from the invention. In reviewing the case, the Supreme Court of the State of North Carolina stated that the underlying issue controlling the result in the case was whether the plaintiffs, being employed by the university, acquired any interest in the invention at the time they discovered it. *See id.* at 680, 319 S.E.2d at 140. The Court reasoned: "If the plaintiffs never had any interest in the process which they developed while employed by the University, the defendant did not stand in a fiduciary relationship to the plaintiffs with regard to the process." *Id.* In deciding whether plaintiffs possessed an interest in the invention sufficient to create a fiduciary relationship, the *Speck* court found several factors important. First, plaintiffs had been employed by the university to engage in precisely the type of research that led to the invention. Second, at all times pertinent, the plaintiffs' salaries were paid by the university. Finally, plaintiffs used the university's

facilities and resources to develop the invention. The Court stated that: "Under these facts, the secret process developed through the research of the plaintiffs belonged to the University absent a written contract by the University to assign." *Id.* at 686, 319 S.E.2d at 143. Because the plaintiffs never possessed any interest in the invention, the Court ruled that no fiduciary duty was owed by the university. "Indeed," added the Court, "any fiduciary duty owed with regard to the secret process was owed by the university professor and his assistant to the university in its capacity as the employer that employed them to develop the process." *Id.*, at 687, 319 S.E.2d at 144. In support of its finding that no fiduciary duty was owed by the university on the specific facts of *Speck*, the Court alluded to a policy consideration articulated by the Massachusetts Supreme Judicial Court. *Id.*, at 685, 319 S.E.2d at 143. In *National Development Co. v. Gray*, 55 N.E.2d 783, 787 (1944), the Massachusetts court reasoned that since an employer bears the loss when an employed researcher fails to produce an invention, the employer should own any invention produced when the researcher succeeds. Thus, since the employer bears the risk of loss with respect to an employee's research activities, the employer, not the employee, possesses the interest in the employee's invention. *Speck*, 311 N.C. at 685, 319 S.E.2d at 143.

Defendant Duke University would have this Court interpret *Speck* as establishing a general principle that no fiduciary relationship can exist between university professors and the universities that employ them. However, such an interpretation of *Speck* would be overbroad. Although no fiduciary duty arose from the facts in *Speck*, it is not settled that a fiduciary duty cannot exist between universities and

professors. In fact, the factors upon which the North Carolina Supreme Court based its decision in *Speck*, along with the policy consideration adopted by the court from the Massachusetts court in *National Development Co.*, suggest that a fiduciary relationship could exist between Plaintiff and Defendant in the present case. In *Speck*, the plaintiffs had been hired and provided with resources in order that they might pursue research that would lead to the patented invention that the plaintiffs subsequently produced. In contrast, it is undisputed by the parties in this case that the Mark III and related equipment were developed and patented by Plaintiff before he came to Duke University. Furthermore, Plaintiff's salary was not paid by Defendant during the time he developed the patented equipment at issue since he was employed by Stanford University at that time. Therefore, Plaintiff did not use any of Defendant's resources in developing the patent or equipment at issue. To the extent the *Speck* court reasoned that the plaintiffs in *Speck* could not establish a fiduciary relationship based on the principle that an employee-inventor lacks an interest in any discovery made on his employer's time and resources, it could be similarly reasoned that since Plaintiff developed his patented invention prior to his employment with Duke and completely without the University's resources, Plaintiff possesses an interest in the invention. If Plaintiff can establish that he possesses an interest in the invention, then he can appropriately allege that the University owes him a fiduciary duty at least with respect to that invention.

An application of the policy consideration articulated by the Massachusetts court in *National Development Co.* and adopted by the North Carolina Supreme Court in *Speck*

supports the conclusion that Plaintiff can establish that he has an interest in the invention. This is especially true where, as in the present case, Defendant never bore the risk of loss with respect to the successful development of Plaintiff's patented equipment because the equipment was developed prior to Plaintiff's arrival at Duke. To the contrary, since Defendant did not fund the research and development that produced the invention, Defendant stood only to gain from Plaintiff's use of his patented equipment to secure federal research grants for the University. On the other hand, Plaintiff, by trusting Defendant with his patented equipment, was taking a risk that his equipment would not be utilized properly in furtherance of the research he intended to pursue at the University. These factors constitute that sort of relationship termed fiduciary by the Supreme Court in *Hajmm*: one in which a special confidence is reposed in a party who in equity and good conscience is bound to act in good faith and with due regard to the interest of the party reposing confidence. *Hajmm*, 328 N.C. at 588; 403 S.E.2d at 489. Therefore, the Court finds that Plaintiff has appropriately alleged the existence of a fiduciary relationship. On this basis, the Court also finds that Plaintiff has sufficiently alleged that Defendant violated this fiduciary duty by usurping his research and patented equipment. Accordingly, Plaintiff has adequately stated a claim for misappropriation of business opportunities, and Defendant's 12(b)(6) motion to dismiss Plaintiff's claim is denied.

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D. Count IV: Age Discrimination

Plaintiff's Complaint also includes a claim for age discrimination in violation of the Age Discrimination in Employment Act of 1967, 29 U.S.C. §§ 621 *et seq.* (the "ADEA"). Defendant has moved for dismissal of Plaintiff's ADEA claim pursuant to Fed. R. Civ. P. 12(b)(6). The ADEA provides that "[i]t shall be unlawful for an employer . . . to fail or refuse to hire or to discharge an individual or otherwise discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's age." 29 U.S.C. § 623(a)(1). The age-based protections of the ADEA are "limited to individuals who are at least 40 years of age." 29 U.S.C. § 631.

The Fourth Circuit has outlined two methods by which a plaintiff may establish a case for age discrimination: (1) by alleging facts which suggest either direct or indirect evidence of a stated purpose to discriminate, or (2) by meeting the factors established in *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 36 L. Ed. 2d 668 (1973). *See E.E.O.C. v. Clay Printing Co.*, 955 F.2d 936, 940 (4th Cir. 1992) (stating that a plaintiff can establish a claim under the ADEA either with direct or indirect evidence of a stated purpose to discriminate or by resorting to the *McDonnell Douglas* scheme). Under the first method of establishing an ADEA claim, the essential elements which must be alleged are (1) that an employee covered by the Act (2) has suffered an unfavorable employment action by an employer covered by the Act (3) under circumstances in which the employee's age was a determining factor in the action in the sense that "but for"

his employer's motive to discriminate against him because of his age, he would not have suffered the unfavorable employment action. *Lovelace v. Sherwin-Williams Co.*, 681 F.2d 230, 238 (4th Cir. 1982).

Under the *McDonnell Douglas* framework, Plaintiff must establish that: (1) he is a member of a protected class, (2) he suffered an adverse employment action, (3) at the time of the adverse employment action, he was performing at a satisfactory level, meeting his employer's legitimate expectations, and (4) plaintiff was replaced by someone substantially younger than the plaintiff.[3] The fourth element

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3. The fourth element of the *McDonnell Douglas* framework has been changed by virtue of the Supreme Court's decision in *O'Connor v. Consolidated Coin Caterers Corp.*, 517 U.S. 308, 116 S.Ct. 1307, 134 L.Ed.2d 433 (1996). The Court held that the requirement that a plaintiff allege that someone below age forty replaced him in order to establish a prima facie claim for age discrimination under the ADEA was not logical. The Court wrote:

> As the very name "prima facie case" suggests, there must be at least a logical connection between each element of the prima facie case and the illegal discrimination for which it establishes a "legally mandatory, rebuttable presumption." The element of replacement by someone under 40 fails this requirement. The discrimination prohibited by the ADEA is discrimination "because of [an] individual's age," 29 U.S.C. § 623(a)(1), though the prohibition is "limited to individuals who are at least 40 years of age," § 631(a). This language does not ban discrimination against employees because they are aged 40 or older; it bans discrimination against employees because of their age, but limits the protected class to

(Cont'd)

can be satisfied either by showing that persons outside the protected class were retained in the same position or by producing some other evidence indicating that the employer did not treat age neutrally. *E.E.O.C. v. Western Electric*, 713 F.2d 1011, 1014-15 (1983). Thus, as to the *McDonnell Douglas* scheme, Plaintiff can satisfy the standard by showing that Defendant treated him differently than younger employees in similar positions.

With respect to Plaintiff's ADEA claim, there are two issues in dispute between the parties. The first is whether Plaintiff was required to allege that he was replaced by someone substantially younger than himself. The second is whether Plaintiff's pleading properly alleges that he suffered an adverse employment action as required under both methods of establishing an ADEA claim. As stated earlier, the Fourth Circuit has held that a plaintiff may establish a claim for age discrimination in one of two ways: with direct or indirect evidence of a stated purpose to discriminate, or through the *McDonnell Douglas* method. However, Plaintiff has worded his ADEA claim in such a way that the Court is left uncertain regarding which method Plaintiff intended to employ. Specifically, Plaintiff's ADEA claim is expressed in one sentence which states: "Dr. Madey's age and his status as a senior faculty member and research

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(Cont'd)

> those who are 40 or older. . . . [T]he fact that a replacement is substantially younger than the plaintiff is a far more reliable indicator of age discrimination than is the fact that the plaintiff was replaced by someone outside the protected class. *O'Connor*, 517 U.S. at 312, 116 S.Ct. at 1310.

scientist were determining factors of the discriminatory action taken by Duke as alleged in paragraphs 29 - 63 above, and are in violation of the Age Discrimination in Employment Act of 1967 ('A.D.E.A.') 29 U.S.C. §§ 621-634." (Plain. First Amend. Supp. Comp. at ¶ 107.) Since it is unclear from Plaintiff's complaint which of the two pleading methods he intended to employ, the Court will evaluate Plaintiff's ADEA claim under the requirements of both methods.

With respect to the method of establishing an ADEA claim through direct or indirect evidence of a stated purpose to discriminate, it is undisputed by the parties in this case that Defendant (the employer) and Plaintiff (the employee) are covered by the act. Therefore, the issue before this Court is whether Plaintiff has properly alleged under the direct evidence method of proof that his age was a determining factor in Defendant's removal of Plaintiff from his position as Director of the FEL Lab in the sense that "but for" Defendant's motive to discriminate against Plaintiff because of his age Plaintiff would not have been removed from his position. *Clay Printing Co.*, 955 F.2d 936, 940-41 (4th Cir. 1992); *Lovelace v. Sherwin-Williams Co.*, 681 F.2d 230, 238 (4th Cir. 1982). Although it is true that stating a discrimination claim so as to avoid dismissal under 12(b)(6) only requires notice pleading, a plaintiff's complaint must allege some facts upon which the discrimination claim is based. *Dugan v. Martin Marietta Aerospace*, 760 F.2d 397, 399 (2d Cir. 1985) (citing *Albany Welfare Rights Organization Day Care Center, Inc. v. Schreck*, 463 F.2d 620, 622-623 (2d Cir. 1972), *cert. denied*, 410 U.S. 944, 93 S.Ct. 1393 (1973) (ruling that a complaint was properly dismissed in a civil rights case where plaintiff made only conclusory

allegations)). The complaint reviewed by the Second Circuit in *Dugan* contained no factual allegations, apart from the plaintiff's age, that supported his assertion of age discrimination. In affirming the district court's dismissal of the complaint pursuant to 12 (b)(6), the court stated: "While a claim made under the ADEA need not contain every supporting detail, it must at least inform the court and the defendant generally of the reasons the plaintiff believes age discrimination has been practiced." *Dugan*, 760 F.2d at 399. In the present case, Plaintiff's allegation of age discrimination states Plaintiff's age, but does not offer any additional facts or direct evidence that would give the Court or Defendant any reason why Plaintiff believes that Defendant's actions in removing Plaintiff from his position as Director of the FEL Lab were motivated by age discrimination. Thus, Plaintiff fails to state a claim of age discrimination as required by the method for stating an ADEA claim with direct evidence.

Plaintiff's failure to state some factual basis in alleging age discrimination in violation of the ADEA also proves fatal to his claim when the claim is reviewed under the *McDonnell Douglas* framework. In order to satisfy the requirements of the *McDonnell Douglas* method of establishing an ADEA claim, Plaintiff would have to allege that he was performing at a satisfactory level that met his employer's expectations and that he was replaced by a substantially younger person. Plaintiff fails to allege facts that would satisfy either of these requirements. As to the issue of Plaintiff's job performance, Plaintiff makes no statement to indicate that he was performing at a satisfactory level that met his employer's expectations. Regarding his replacement by another person,

Plaintiff makes three statements. First, he states that former Chairman of the Department of Physics Lawrence Evans recruited "an untenured, faculty member, Bobby Guenther," to accept the position of Director of the FEL Lab. (Plain. First Amend. Supp. Comp. at ¶ 34.) Second, he states that an "adjunct, untenured faculty member of the Physics Department who agreed with and championed the changed plans for the FEL Lab" was selected as a "second director." (*Id.* at ¶ 43.) Third, he states that Department Chair Berndt Mueller was appointed to replace Plaintiff as Principal Investigator of the ONR Grant. (*Id.* at ¶ 56.) However, Plaintiff never states that Guenther or Mueller are younger than he is. Consequently, Plaintiff's complaint also fails to provide sufficient allegations to comply with the *McDonnell Douglas* method of alleging a claim of age discrimination under the ADEA. Since Plaintiff has failed to properly state a claim under either method available to him to establish age discrimination, Defendant's motion to dismiss Plaintiff's age discrimination claim pursuant to 12(b)(6) is granted.

E. Count V: Civil Rights Violations under 42 U.S.C. § 1983

Plaintiff alleges that in response to his accusations that the Duke University administration was improperly diverting federal research funds and creating health and safety hazards through misuse of the technology of the FEL Lab, Defendant removed him from his position as principal investigator of the ONR grant and eliminated his access to the lab. Plaintiff claims that these actions subjected him to a deprivation of his First Amendment rights in violation of 42 U.S.C. § 1983. Defendant's 12(b)(6) motion to dismiss addresses Plaintiff's § 1983 claim as well.

Appendix C

Title 42 U.S.C. § 1983 provides in part:

> Every person who, under color of any statute, ordinance, regulation, custom, or usage, *of any State or Territory or the District of Columbia*, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress. . . .

42 U.S.C. § 1983.

In *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937, 102 S.Ct. 2744, 2753 (1982), the Supreme Court of the United States held that an action pursuant to § 1983 must involve the deprivation of a federal right and must be "fairly attributable to the State." *Lugar*, 457 U.S. 922, 937, 102 S.Ct. 2744, 2753. Fair attribution to the state is a two-step process. The Court stated:

> First, the deprivation must be caused by the exercise of some right or privilege created by the State or by a rule of conduct imposed by the state or by a person for whom the State is responsible. . . . Second, the party charged with the deprivation must be a person who may fairly be said to be a state actor. This may be because he is a state official, because he has acted together

> with or has obtained significant aid from state officials, or because his conduct is otherwise chargeable to the State.

Lugar, 457 U.S. 922, 937, 102 S.Ct. 2744, 2753.

In support of its 12(b)(6) motion to dismiss, Defendant argues that Plaintiff's claim does not allege state action that covers Defendant's action in this case. Specifically, Defendant contends that, contrary to Plaintiff's argument, any funds that flow to Duke University from the lab's research grants do not implicate § 1983. (Def.'s Mot. Dis. First Amend. Supp. Comp. at 14-15.) First, the funds come from the federal government rather than the state government, and § 1983 clearly applies to actions pursuant to state law, not federal law. *Kotmair v. Gray*, 505 F.2d 744, 746 (4th Cir. 1974) (ruling that internal revenue agents who, pursuant to federal statute, caused levy to be placed on taxpayer's bank account to collect penalty for late payment of federal employment taxes were not acting "under color of state law" and thus were not subject to suit for deprivation of civil rights). Second, even if the research funds had come from state sources, such state funding would not be sufficient to establish state action. In *Rendell-Baker v. Kohn*, 457 U.S. 830, 92 S.Ct. 1965 (1982), the Supreme Court held that a private school's receipt of public funds did not make its decision to discharge teachers an act of the State for the purposes of § 1983. The Court stated that "[t]he school, like the nursing homes, is not fundamentally different from many private corporations whose business depends primarily on contracts to build roads, bridges, dams, ships, or submarines for the government. Acts of such private contractors do not

become acts of the government by reason of their significant or even total engagement in performing public contracts." *Rendell-Baker v. Kohn*, 457 U.S. at 840-41, 92 S.Ct. at 1971. Plaintiff, however, relies on *Burton v. Wilmington Parking Authority*, 365 U.S. 715, 81 S.Ct. 856 (1961), where the Court stated:

> [T]o fashion and apply a precise formula for recognition of state responsibility under the Equal Protection Clause is an "impossible task" which "This [sic] Court has never attempted." *Kotch v. Board of River Port Pilot Com'rs*, 330 U.S. 552, 556, 67 S.Ct. 910, 912 (1947). Only by sifting facts and weighing circumstances can the nonobvious involvement of the State in private conduct be attributed its true significance.

Burton, 365 U.S. at 722, 81 S.Ct. at 860.

Though the Court acknowledges the need to examine the circumstances underlying a § 1983 claim for nonobvious state involvement, there must exist at least some facts which support a finding of the existence of state actors. Without such facts, the state action requirement of § 1983 cannot be satisfied. In the present case, Plaintiff presents no factual allegations that he was deprived of a legitimate federal right by state actors acting under color of state law. Accordingly, Defendant's 12(b)(6) motion to dismiss Plaintiff's § 1983 claim is granted.

Appendix C

F. Count VI: Constructive Fraud

(1) Failure to Plead With Particularity Required By Rule 9(b)

Plaintiff alleges that Defendant's actions in removing him from his position as Director of the FEL Lab and Principal Investigator of the ONR grant, as well as seizing exclusive control of the Mark III and related equipment constitute constructive fraud. Defendant first moves for dismissal of the constructive fraud claim on the grounds that Plaintiff fails to plead with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure. Defendant additionally contends that Plaintiff's allegations fail to state a claim for constructive fraud. Rule 9(b) states:

> (b) In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally.

Fed. R. Civ. P. 9(b).

With respect to general claims of fraud, this Court has interpreted Rule 9(b) to require a pleading of the "time, place, and contents of the alleged fraudulent misrepresentation, as well as the identity of each person making the misrepresentation and what was obtained thereby." *Breeden v. Richmond Community College*, 171 F.R.D. 189, 195 (M.D.N.C. 1997) (quoting *Riley v. Murdock*, 828 F.Supp. 1215, 1225 (E.D.N.C.1993)) (citations omitted). The purpose of Rule 9(b) is to give a defendant sufficient notice of the misconduct that forms the basis of the claim for fraud, thereby allowing the defendant ample

opportunity to prepare a defense. *Andrews v. Fitzgerald*, 823 F.Supp. 356, 373 (M.D.N.C. 1993). Although the Federal Rules of Civil Procedure determine the pleading requirements in federal civil suits, where a plaintiff brings a state claim, the federal rules cannot require the pleading of elements beyond those established by state law. To allow otherwise would result in an alteration of the substance of the state law at issue. In this instance, Rule 9(b) simply requires that Plaintiff plead the elements of constructive fraud established by North Carolina law.

In support of this principle, Plaintiff cites *Terry v. Terry*, 302 N.C. 77, 85, 273 S.E.2d 674, 678-79 (1981) for the proposition that a pleading of constructive fraud satisfies the particularity requirements of the pleading rules, such as Rule 9(b), in a manner different from other fraud claims. *Terry*, 302 N.C. 77, 85, 273 S.E.2d 674, 678-79. In *Terry*, the North Carolina Supreme Court stated:

> A constructive fraud claim requires even less particularity because it is based on a confidential relationship rather than a specific misrepresentation. The very nature of constructive fraud defies specific and concise allegations and the particularity requirement may be met by alleging facts and circumstances "(1) which created the relation of trust and confidence, and (2) [which] led up to and surrounded the consummation of the transaction in which defendant is alleged to have taken advantage of his position of trust to the hurt of plaintiff."

Terry, 302 N.C. 77, 85, 273 S.E.2d 674, 678-79 (quoting *Rhodes v. Jones*, 232 N.C. 547, 548-49, 61 S.E.2d 725 (1950)).

Thus, in order to comply with *Terry*, the Court finds that Plaintiff must allege the existence of facts and circumstances which created a relationship of trust between Plaintiff and Defendant, as well as facts and circumstances which allege the manner in which Defendant violated its fiduciary duty to Plaintiff. In alleging in detail how he was enticed to come to Duke University, Plaintiff has clearly stated the circumstances that created the relationship of trust between Plaintiff and Duke, particularly as that relationship of trust is set out in the terms of his Research Agreement with the University. (Plain. First Amend. Supp. Comp. at ¶¶ 11-16.) Additionally, Plaintiff has alleged in detail those events that led to his removal from his position as Director of the FEL Lab and Principal Investigator for the federal research grant.[4] (*Id.* at ¶¶ 29-63.) Therefore, this Court finds that in light of *Terry*, Plaintiff's claim of constructive fraud satisfies the particularity requirement of Rule 9(b).

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4. As explained *supra*, Plaintiff alleges that the Defendant revised the plans for construction of the FEL Lab facilities in order to pursue the research of other professors in the Physics Department. Plaintiff claims that when he objected to the changed plans, members of the University faculty conceived of a plan to remove Plaintiff from his position of authority. First, a second Director was appointed to run the lab along with Plaintiff, thereby creating a situation wherein Plaintiff's objections to changes within the Lab could be neutralized by the second Director. (Plain. First Amend. Supp. Comp. at ¶ 43.) Second, Plaintiff claims that Defendant University created an advisory committee, composed of senior administrators committed to the changed plans advocated by Defendant. This committee would have the power to veto decisions made by Plaintiff. (*Id.* at ¶ 44.) Finally, Plaintiff alleged that after he objected to these changes in the management of the Lab, Defendant removed him from his position as Director of the Lab and petitioned the Office of Naval Research to remove Plaintiff from his position as Principal Investigator of the ONR Grant. (*Id.* at ¶ 52-26.)

Appendix C

2. Defendant's 12(b)(6) Motion to Dismiss the Constructive Fraud Claim

In the alternative, Defendant argues that Plaintiff's claim for constructive fraud should be dismissed for failure to state a claim under 12(b)(6). Defendant argues that under North Carolina law constructive fraud requires a fiduciary relationship. Defendant contends that Plaintiff has failed to establish the existence of a fiduciary relationship, and therefore fails to state a claim for constructive fraud. With respect to this argument, it bears repeating that the facts alleged by Plaintiff constitute the sort of relationship termed fiduciary by the North Carolina Supreme Court in *Hajmm* where a special confidence is reposed in the parties who in equity and good conscience are bound to act in good faith and with due regard to the interest of the other party. *Hajmm*, 328 N.C. at 588, 403 S.E.2d at 489. Thus, to the extent that Plaintiff has effectively alleged the existence of a fiduciary relationship based upon *Hajmm*, Defendant's 12(b)(6) motion to dismiss Plaintiff's constructive fraud claim is denied.

G. Count VII: Breach of Contract

Plaintiff has brought a breach of contract claim against Defendant based on three factors. First, Plaintiff claims that Defendant's actions in removing Plaintiff from his position as Director of the FEL Lab and Principal Investigator of the ONR Grant is a violation of Defendant's agreement with Plaintiff. (Plain. First Amend. Supp. Comp. at ¶ 130.) Second, Plaintiff claims that Defendant's actions in denying Plaintiff access to and control of the Mark III FEL equipment is a violation of the Agreement. (*Id.*) Third, Plaintiff claims

that the due process rights accorded to faculty members in decisions affecting their status and employment at Duke were incorporated into the Research Agreement, and Defendant's action in depriving Plaintiff of those rights constitutes a violation of the Agreement. (*Id.* at ¶ 131.)

Defendant moves for a 12(b)(6) dismissal of Plaintiff's claim for breach of contract on two bases. First, Defendant disagrees with Plaintiff regarding what terms are actually included in the Research Agreement. Although Defendant does not dispute that it removed Plaintiff from his position as Director of the FEL Lab and Principal Investigator of the ONR Grant, Defendant contends that there are no terms in the Research Agreement that these actions violate. For example, Defendant states that the Research Agreement does not include a term that gives Plaintiff due process rights with respect to decisions made by Defendant that affect Plaintiff's employment. (Def. Mot. Dis. Plain. First Amend. Supp. Comp. at 18.) As to what terms are actually included in the Research Agreement, it appears that the text of the Agreement has not been made a part of the record. However, the Court reiterates that in reviewing a 12(b) (6) motion, the Court is to accept as true all well-pleaded factual allegations. *Randall v. United States*, 30 F.3d 518, 522 (4th Cir. 1994), *cert. denied*, 514 U.S. 1107, 131 L.Ed. 2d 849 (1995). Accordingly, the Court accepts as true Plaintiff's allegation that the Research Agreement provided that Plaintiff would direct the activities of the FEL Lab. (Plain. First Amend. Supp. Comp. at ¶ 16(a-i.)) To the extent that Defendant removed Plaintiff from his position of authority in the FEL Lab and denied Plaintiff access to the Lab, Plaintiff has properly stated a claim such that dismissal of his breach of contract claim pursuant to 12(b)(6) is not warranted.

Second, Defendant argues that because the Research Agreement is an employment contract, Plaintiff's claim for breach of contract is flawed under North Carolina law. (*Id.* at 18.) Defendant supports this assertion by arguing that under North Carolina law an employment contract is terminable at will unless it includes a provision stating that it is a term agreement or some other agreement other than a contract terminable at will. In reviewing this argument, the Court notes that, unlike most litigation regarding contracts that are terminable at will, the issue here is not whether Plaintiff's employment was terminable at will. In the present case, Plaintiff's employment was not terminated, but rather Plaintiff contends that the conditions of his employment were altered such that his status within the FEL Lab at Duke University was changed. Plaintiff claims that Defendant's actions in altering Plaintiff's employment status constitute a breach of the terms of the Research Agreement. Defendant's reasoning suggests that if the Research Agreement is an employment contract that is terminable at will, then all terms in the Research Agreement related to Plaintiff's employment are likewise terminable at will, and therefore not binding upon Defendant if Defendant chooses to terminate the contract. This reasoning is not consistent with this Court's interpretation of the nature of contracts of employment at will under North Carolina law.

Under North Carolina law, "where a contract of employment contains no provision as to duration, the contract is terminable at the option of the employer ('at will'), without regard to cause." *Fortsmann v. Culp*, 648 F.Supp. 1379, 1382 (M.D.N.C. 1986) (citing *Nantz v. Employment Securities Commission*, 290 N.C. 473, 226 S.E.2d 340 (1976); *Smith v.*

Ford Motor Co., 289 N.C. 71, 221 S.E.2d 282, 79 A.L.R.3d 651 (1976); *Malever v. Kay Jewelry Co.*, 223 N.C. 148, 25 S.E.2d 436 (1943)). Even where the parties enter into a contract for "permanent employment," the contract is an "indefinite general hiring" terminable at will in the absence of an additional expression as to duration. *Fortsmann*, 648 F.Supp. at 1382. (citing *Roberts v. Wake Forest University*, 55 N.C.App. 430, 286 S.E.2d 120, *review denied*, 305 N.C. 586, 292 S.E.2d 571 (1982.))[5] It is important to note,

5. The Court notes that the Research Agreement may not in this instance be viewed as an employment contract terminable at will, though this is not central to addressing Plaintiffs breach of contract claim. Where an employee is employed for a definite term or is subject to discharge only for "just cause," the employment contract is not terminable at will. *Wagoner v. Elkin CitySchools' Board of Education*, 113 N.C.App. 579, 440 S.E.2d 119, *disc. review denied*, 336 N.C. 615, 447 S.E.2d 414 (1994). In *Wagoner*, where the plaintiff had attained the status of "career teacher" under N.C.Cen.Stat. § 115C-325(c), a status which required that the school system follow prescribed procedures in order to terminate the plaintiff, the court found that the plaintiff was not an employee at will. Consequently, the proper claim for the plaintiff upon being discharged in a manner inconsistent with the due process requirements of § 115C-325(c) was a breach of contract claim. *Wagoner*, 113 N.C.App. at 588, 440 S.E.2d at 125. In the present case, Plaintiff alleges that the Research Agreement gave him status as a tenured professor at Duke University and incorporated the due process rights afforded to tenured faculty by the Duke University Faculty Handbook. The Handbook is not included as an exhibit in the pleadings of either party in this case, therefore, the Court is unable to review its terms. However, the incorporation of the document into the Research Agreement could mean that the University would be required to follow proscribed procedures in order to terminate Plaintiff, and would only be able to do so for those reasons outlined in the Handbook. In such a case, the Research Agreement would not be an employment contract terminable at will.

however, that although the employment-at-will doctrine allows employers to terminate an employee at will, the North Carolina courts have expressly stated that an employer may not disregard supplemental terms contained in an employment-at-will contract, such terms being themselves enforceable under contract law. *Walker v. Westinghouse Elec. Corp.*, 77 N.C.App. 253, 261, 335 S.E.2d 79, 84 (N.C.App. 1985); *Harris v. Duke Power Co.*, 83 N.C.App. 195, 197, 349 S.E.2d 394, 395 (N.C.App. 1986). As an illustration of this principle, the *Walker* court reviewed the decision of the North Carolina Supreme Court in *Roberts v. Mills*, 184 N.C. 406, 114 S.E. 530 (1922). In *Roberts*, an employer offered in January to pay a 10% bonus at Christmas of the same year to employees employed continuously during that year. The plaintiff was discharged in September without bonus pay. The plaintiff alleged that he had intended to quit his job in January but stayed on because of the bonus. The Court ruled that while the agreement did not alter the terminable-at-will nature of the employment contract, it did confer upon plaintiff an enforceable right to the bonus earned up to the time of discharge.

In the present case, Plaintiff alleges that the Research Agreement included a specific term which guaranteed that Plaintiff would control the activities of the FEL Lab and the equipment which Plaintiff brought to the University for use in the Lab. Plaintiff also alleges that the Research Agreement included a specific term which guaranteed Plaintiff due process rights with respect to any decision affecting his employment status. Under North Carolina law, even if the overall Research Agreement were an employment-at-will contract as Defendant alleges, the terms of employment

contained in the contract would still be enforceable by Plaintiff against Defendant provided those terms were themselves enforceable under contract law. *Walker*, 77 N.C.App. at 261, 335 S.E.2d at 84; *Harris*, 83 N.C.App. at 197, 349 S.E.2d at 395. Therefore, to the extent that such a defined employment relationship existed, based upon the specific terms of the Research Agreement, Plaintiff could appropriately assert that a breach of contract had occurred. Based upon the facts of this case, Defendant's motion to dismiss Plaintiff's breach of contract claim, specifically the Research Agreement, is denied to the extent the breach of contract claim is based upon the Research Agreement as represented to the Court.

VIII. CONCLUSION

For the foregoing reasons, the Individual Defendants' Motion to Dismiss Plaintiff's First Amended and Supplemental Complaint [Document #31], as alleged against them individually pursuant to Rule 8 of the Federal Rules of Civil Procedure, is GRANTED. The Court's ruling on Defendant Duke University's Motion to Dismiss Counts One, Three, Four, Five, Six and Seven of Plaintiff's First Amended and Supplemental Complaint [Document #30] is as follows:

Defendant Duke University's motion to dismiss Plaintiff's claim of infringement of the '103 patent (Count I) is GRANTED in part and DENIED in part. The motion is granted with respect to Plaintiff's infringement claims which are based upon allegations of patent use by Defendant Duke University pursuant to government research grants issued to the University. However, Defendant's motion is denied with

respect to Defendant's alleged use of the patent for private purposes outside the scope of the government's retained right in the patent.

Furthermore, for the reasons previously stated, Defendant Duke University's motion to dismiss Plaintiff's claims for conversion and misappropriation of business opportunities (Count III) is DENIED. Defendant Duke University's motion to dismiss Plaintiff's claim for age discrimination in violation of the ADEA (Count IV) is GRANTED. Defendant Duke University's motion to dismiss Plaintiff's claim for deprivation of First Amendment rights in violation of § 1983 (Count V) is GRANTED. Defendant Duke University's motion to dismiss Plaintiff's claim for constructive fraud (Count VI) is DENIED. Defendant Duke University's motion to dismiss Plaintiff's claim for breach of contract (Count VII) is DENIED. In light of these rulings, Plaintiff and Defendant Duke University are directed to proceed with the prosecution and defense of this matter with respect to Plaintiff's claims for patent infringement, conversion, misappropriation of business opportunities, and breach of contract.

An Order and Judgment in accordance with this Memorandum Opinion will be filed contemporaneously herewith.

This the 1st day of December, 1999.

s/ James A. Beaty
United States District Judge

Appendix C

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

1:97CV1170

JOHN M. J. MADEY,

Plaintiff,

v.

DUKE UNIVERSITY, CHARLES E. PUTMAN, JOHN STROHBEHN, WILLIAM H. CHAFE, BERNDT MUELLER, BOBBY GUENTHER, and LAWRENCE EVANS

Defendants.

ORDER AND JUDGMENT

BEATY, District Judge.

This matter is before the Court on the separate motions of Defendant Duke University [Document #30] and Duke Individual Defendants [Document #31], in which both parties move to dismiss John M. J. Madey's First Amended and Supplemental Complaint [Document # 28] pursuant to Rules 8, 9(b), 12(b)(1), 12(b)(6) and 12(h)(3) of the Federal Rules of Civil Procedure.[1] Plaintiff's Complaint includes

1. The individual Defendants in this action are Charles E. Putman, John Strohbehn, William H. Chafe, Berndt Mueller, Bobby Guenther and Lawrence Evans.

claims for infringement of two patents (Counts I and II); conversion of property and misappropriation of business opportunities (Count III); violation of 29 U.S.C. §§ 621-634, the Age Discrimination in Employment Act ("the ADEA") (Count IV); violation of Plaintiff's civil rights as protected under 42 U.S.C. § 1983 (Count V); constructive fraud (Count VI); and breach of contract (Count VII). For the reasons enumerated in the MEMORANDUM OPINION filed contemporaneously herewith, based upon the Court's review of the motions and supporting memoranda of all parties, the Individual Defendants' Motion to Dismiss Plaintiffs First Amended and Supplemental Complaint [Document #31], as alleged against them individually pursuant to Rule 8 of the Federal Rules of Civil Procedure, is GRANTED. The Court's ruling on Defendant Duke University's Motion to Dismiss Counts One, Three, Four, Five, Six and Seven of Plaintiff's First Amended and Supplemental Complaint [Document #30] is as follows:

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Furthermore, for the reasons enumerated in the MEMORANDUM OPINION filed contemporaneously herewith, Defendant Duke University's motion to dismiss Plaintiff's

claims for conversion and misappropriation of business opportunities (Count III) is DENIED. Defendant Duke University's motion to dismiss Plaintiff's claim for age discrimination in violation of the ADEA (Count IV) is GRANTED. Defendant Duke University's motion to dismiss Plaintiff's claim for deprivation of First Amendment rights in violation of § 1983 (Count V) is GRANTED. Defendant Duke University's motion to dismiss Plaintiff's claim for constructive fraud (Count VI) is DENIED. Also, for the reasons enumerated in the MEMORANDUM OPINION filed contemporaneously herewith, Defendant Duke University's motion to dismiss Plaintiff's claim for breach of contract (Count VII) is DENIED. In light of these rulings, Plaintiff and Defendant Duke University are directed to proceed with the prosecution and defense of this matter with respect to Plaintiff's claims for patent infringement, conversion, misappropriation of business opportunities, and breach of contract.

This the 1st day of December, 1999.

s/ James A. Beaty
United States District Judge

Supreme Court, U.S.
FILED
JAN 31 2003
OFFICE OF THE CLERK

(2)

No. 02-1007

In The
Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M. J. MADEY,

Respondent.

On Petition For A Writ Of *Certiorari* To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICI CURIAE* CONSUMER PROJECT ON TECHNOLOGY AND PUBLIC KNOWLEDGE IN SUPPORT OF PETITION FOR WRIT OF *CERTIORARI*

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STATEMENT OF INTERESTS OF *AMICI CURIAE*

This brief *amici curiae* in support of petitioner is submitted pursuant to Rule 37 of the Rules of this Court.[1]

Consumer Project on Technology (CPT) is a public interest non-profit organization founded by Ralph Nader in 1995. CPT represents the public who are the ultimate beneficiaries of the invention of new technologies. CPT seeks to protect the public interest concerning intellectual property law in general, and in the fields of pharmaceuticals and biotechnology, computer software and information services in particular.

Public Knowledge (PK) is a public-interest advocacy organization dedicated to fortifying and defending a vibrant information commons. PK works with a wide spectrum of stakeholders to promote the core conviction that some fundamental democratic principles and cultural values – openness, access, and the capacity to create and compete – must be given new embodiment in the digital age.

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[1] Letters from all parties consenting to the filing of this brief have been filed with the Clerk of this Court. No counsel for a party authored this brief in whole or in part, and no person or entity other than *amici curiae*, or their counsel, made a monetary contribution to the preparation or submission of this brief. American University, Washington College of Law, Glushko-Samuelson Intellectual Property Law Clinic students Nathan Mitchler and Cheree Simpson prepared this work under the supervision of Peter Jaszi and Counsel of Record Joshua Sarnoff.

SUMMARY OF ARGUMENT

The Federal Circuit's narrow interpretation of the experimental use exception in *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002), impedes the "Progress of Science and useful Arts." U.S. Const. Art. I, § 8, cl. 8. Under that interpretation, most basic research will not be viewed as strictly philosophical inquiry or will be viewed as furthering a legitimate business purpose. Scientists will need to license essential patented technologies and other research inputs. As a result, basic research will be foregone or delayed.

Basic research is foundational and leads to further discoveries and important inventions. Knowledge is transferred from basic research to additional basic research, applied research, and technology development. Access to patented technologies and other research inputs is essential for basic research. Patent licensing practices increasingly prevent or discourage access to these inputs, precluding or delaying basic research that leads to life-saving technologies and other benefits.

The experimental use exception, like the fair use doctrine in copyright, is needed to promote progress. Courts have continually shaped copyright fair use to respond to changing circumstances in order to effectuate the basic constitutional purpose. The Court should grant the writ of *certiorari* to ensure that the experimental use exception also promotes the constitutional purpose.

ARGUMENT

I. The Federal Circuit's Decision Frustrates the Constitutional Goal of Patent Law.

The premise of patent law is derived from the Constitution: "To Promote the Progress of Science and useful Arts."[2] A patent gives the owner the right to exclude others from making, using, or selling the invention.[3] The grant of a patent creates a legal monopoly in the invention in order to foster innovation.

"Federal patent laws have embodied a careful balance between the need to promote innovation" and the need to provide access to and use of knowledge to enable further innovation.[4] If patent law too strongly favors incentives for initial invention, it discourages sequential invention.[5] The experimental use doctrine is essential for balance because it creates an exception to patent infringement that protects basic research.[6]

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[2] U.S. Const. Art. I, § 8, cl. 8.

[3] 35 U.S.C § 154(a).

[4] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

[5] *See, e.g., Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928) ("the patent monopoly would thus be extended beyond the discovery, and would discourage rather than promote invention").

[6] *See, e.g., Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000); *Roche Prods. Inc., v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935). *See generally* Donald S. Chisum, Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement, § 16.03[1] (2000); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017 (1989).

The Federal Circuit's narrow interpretation of the experimental use exception in this case[7] frustrates the goals of patent law. Under that court's holding, most basic research will not qualify for the experimental use exception. The Federal Circuit limited the exception to strictly philosophical inquiry, which it viewed narrowly, and held the exception inapplicable when the experimental use furthers the researcher's legitimate business, which it viewed broadly.[8] As a result, basic researchers will be forced to seek licenses for a wide range of technologies and other research inputs protected by patent law.

Basic researchers depend upon access to and use of these inputs to perform their research.[9] Restrictive patent licensing practices can inhibit basic research. Access to or use of research inputs may be restricted by: (1) a refusal to license; (2) increased or insurmountable costs; (3) increased time in licensing negotiations and less time in the lab; and (4) onerous licensing offers that discourage licensing.[10] In these circumstances, basic research is foregone or delayed.

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[7] *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002).

[8] *See id.* at 1361-63.

[9] *See* Eisenberg, *supra* note 6, at 1086-87; Linda J. Demaine & Aaron X. Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of Biotechnology Patent*, 55 Stan. L. Rev. 303, 415 (2002).

[10] *See infra* Section II. D.

II. Basic Research, Scientific Progress, and Public Health Are Threatened by the Federal Circuit's Narrow Interpretation.

Basic research expands knowledge and leads to applied research and to beneficial technology. Under the Federal Circuit's holding, basic research cannot occur without licensing patented technology and other research inputs. Basic research and its fruits are thus foregone or delayed. As a result, the Federal Circuit's narrow interpretation of the experimental use exception will stunt basic research, impede progress, and threaten public health.

A. Basic Research Is Vital to Scientific Progress.

Basic research is performed "to gain fundamental knowledge or understanding of phenomena and observable facts, without specific application toward processes or products."[11] Basic research expands knowledge by fostering new ideas and innovative approaches.[12] In contrast, applied research focuses on solving practical problems and developing targeted solutions.[13] Basic research is untargeted,

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[11] 20 U.S.C. § 9501(3)(A).

[12] *See, e.g.*, Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 Am. Bus. L.J. 187, 192 n.13 (2002) ("The objective of basic research is to gain more comprehensive knowledge or understanding of the subject under study, without specific applications in mind.").

[13] *See, e.g.*, Norman W. Storer, The Social System of Science 16 (1966) ("Basic research is the 'purest' form of scientific activity in that it is focused directly upon . . . 'the extension of certified knowledge' rather than upon the solution of practical problems.") (citation omitted).

and is frequently the precursor of more advanced studies that may lead to the development of revolutionary technologies.[14]

Basic research is performed in various settings. In 2000, universities conducted 43 percent of basic research, accounting for 69 percent of all university research and development expenditures. fifty-seven percent of basic research occurred outside of universities.[15]

Basic research has contributed to, and will continue to contribute to, important discoveries and inventions such as the x-ray, the polio vaccine, and genetic engineering.[16] Many advances in medical technology trace their origin to basic research. For example, a study asked ninety physicians to name the most important developments in cardiovascular-pulmonary medicine. The study concluded that 42 percent of the "conceptual steps" of the ten "most important medical treatments," began as basic research by scientists who did not intend to focus their research on that specific disease.[17]

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[14] *See infra* Section II. B.

[15] *See* National Science Foundation, *Science and Engineering Indicators 2002, Academic Research and Development, Highlights, Financial Resources for Academic R&D, at* www.nsf.gov (last visited Jan. 12, 2003).

[16] *See* Arthur Kornberg, *Basic Research, the Lifeline of Medicine, at* www.nobel.se/cgi-bin (last visited Jan. 19, 2003).

[17] National Institute General Medical Sciences, National Institutes of Health, *Why Do Basic Research?, at* www.nigms.nih.gov/news/science_ed/whydo.html (last visited Jan. 19, 2003) [hereinafter cited as *Why Do Basic Research?*]. Three of the most important inventions cited were open-heart surgery, blood vessel surgery, and the drug treatment of hypertension. *See id.*

B. Basic Research Leads to Important Technologies.

Basic research is foundational research. Basic research is essential to applied research and development of important technologies. Information flows from basic research to applied research, and both rely on previous innovations.[18] As Sir Isaac Newton stated, "If I have seen far, it is by standing on the shoulders of giants."[19] If essential prior innovations are not available to complete basic research, then applied research and resulting technological innovations also will be impeded.

Basic research is routinely used in applied research and technology development. For example, in 2000, over 200 universities transferred research to the commercial sector, eight times more than in 1980.[20] In turn, the commercial sector used the information for further basic research, applied research, and technology development.

This flow of information benefits the public. For example, the transfer of knowledge from basic research to applied research to pharmaceutical product development has resulted in important new treatments for "hemophilia, anemia, cystic fibrosis, multiple sclerosis and

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[18] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 698-99 (1998).

[19] *See generally* Robert K. Merton, On the Shoulders of Giants: A Shandean Postscript (Free Press 1965).

[20] *See* Douglas W. Jamison & Christiana Jansen, *Technology Transfer and Economic Growth*, 12 J. Assoc. of Univ. Tech. Managers (2000), *at* www.autm.net/pubs/journal/01/techtransfer.html (last visited Jan. 18, 2003).

heart attacks."[21] Basic research also has led to the discovery and commercial availability of tests for breast cancer and osteoporosis.[22]

Basic research often opens creative fields for future basic and applied research. In 1973, Stanley Cohen and Herbert Boyer invented a method of gene splicing that revolutionized biological research and launched the biotechnology industry.[23] The patent for their gene splicing method was licensed to numerous university, non-profit, and commercial research facilities, including 467 companies.[24] Because this invention was readily licensed and available, innovative products were created such as "insulin for the treatment of diabetes, growth hormone for children with growth deficiencies, and interferon for cancer patients."[25] These developments would not have taken place if Cohen and Boyer had not widely licensed their patent. Without a broad experimental use exception, Cohen and Boyer would have been unable to perform their research if they had been denied the use of essential patented technologies or research inputs.

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[21] Association of University Technology Managers, *Technology Transfer Adds $21 Billion to Economy and Supports 180,000 Jobs a Year* (1997), *at* www.autm.net/pubs/survey/autmre12.html (last visited Jan. 12, 2003).

[22] *See id.*

[23] *See* Stanley N. Cohen, *et al.*, *Construction of Biologically Functional Bacterial Plasmids* In Vitro, 70 Proc. Nat'l Acad. Sci. 3240 (1973).

[24] *See* Law & Technology at GW (George Washington University), *Bertram Rowland and the Cohen/Boyer Cloning Patent*, *at* www.law.gwu.edu/tech/rowland.asp (last visited Jan. 10, 2003).

[25] *Id.*

C. Genetic Research Demonstrates Why Access to Patentable Inputs Is Critical for Basic Research in All Sciences.

Access to technologies and other research inputs is essential for foundational scientific inquiry. Genetic research provides a useful example of a field where such as access is needed. Modern genetic research began with the disclosure in 1953 by James Watson and Francis Crick of the structure of deoxyribonucleic acid.[26] Their discovery led to many advances in genetic research, including the gene splicing methods of Cohen and Boyer. In turn, those methods were used to develop and produce disease-treating materials, such as insulin and growth hormone.[27]

Current basic genetic research requires many technologies and other research inputs that are the subject of patents. For example, such research may require: animal and human gene sequences; bacterial and viral cultures; cell lines; chemical reagents; computerized instruments; data-processing software; diagnostic equipment and materials; gene marking chemicals; gene splicing methods; and laboratory containers and equipment.[28] The need for access to and use of such basic research inputs is more pressing than ever.

In the last two decades, the number of patents has increased dramatically.[29] Subsequent to Cohen and Boyer's

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[26] *See* James D. Watson, The Double Helix: A Personal Account of the Discovery of the Structure of DNA (1968).

[27] *See Why Do Basic Research?*, *supra* note 17.

[28] *See generally* Horace F. Judson, The Eighth Day of Creation: Makers of the Revolution in Biology (1979).

[29] *See, e.g.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1497-98 (2001).

invention, patents became readily available for the results of genetic research.[30] In 2002, the number of biotechnology patents issued numbered over 13,500.[31] As of 2000, the U.S. Patent Trademark Office had granted more than 1,000 patents on human genes and 20,000 more were pending.[32] Many of these patented inventions are necessary for further basic genetic research.

If basic researchers are unable to obtain access to and use of these necessary inputs, their research will be frustrated.[33] This risk is now greater than ever. As the former head of the National Institutes of Health warned in regard to patenting basic research inputs: "[s]uch practices can have detrimental effects on science and its delivery of health benefits."[34]

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[30] *See Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[31] *See* Biotechnology Industry Organization, *Biotechnology Industry Statistics, Guide to Biotechnology, at* www.bio.org/er/ (last visited Jan. 18, 2003).

[32] *See* Merrill Goozner, *Patenting Life*, The American Prospect 26, Dec. 18, 2000.

[33] *See, e.g.*, Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. Rev. 1623, 1670 (2001).

[34] *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary*, 106th Cong. 83 (2000) (Statement of Harold Varmus, President of the Memorial Sloan-Kettering Cancer Center).

D. Patent Licensing Practices Increasingly Block Basic Research.

Licensing practices can create an environment where basic research will not occur.[35] "Patents have a long tradition of being used to *prevent* innovation."[36] Patents are increasingly sought with the intent of creating portfolios (or thickets) to prevent competition.[37] Patent holders may refuse to license necessary inputs to basic research.[38]

The very need to obtain a license may frustrate basic research. Licenses are costly. Licenses must be negotiated, incurring transaction costs and diverting attention from research. Licensing offers may contain restrictions that discourage licensing.

Many basic researchers cannot afford the expense of licensing fees. For example, genetic research scientists may be unable to afford necessary patented gene sequences and

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[35] *See, e.g.*, Heller & Eisenberg, *supra*, note 18, *passim*; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 1, 10-12 (2002).

[36] James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies* 4 (2002), *at* www.papers.ssn.com/sol3/papers-cfm?abstract_id=327760 (last visited Jan. 29, 2003).

[37] *See, e.g.*, Wesley M. Cohen, *et al.*, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)*, National Bureau of Economic Research Working Paper Series 26 (2000); Bessen, *supra* note 36.

[38] *See, e.g.*, Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 Berkeley Tech. L.J. 813, 845-853 (2001). *See generally* John H. Barton, *Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios*, 69 Antitrust L.J. 851, 854, 866 (2002); Marina Lao, *Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty To Deal*, 9 Cornell J. L. & Pub. Policy 193, 202-06, 217-18 (1999).

gene splicing methods. Scientists at Bristol-Meyers Squibb – a well-funded commercial enterprise – were unable to license essential inputs to their cancer research because of the royalty rates demanded by patent holders.[39] Pharmaceutical firms routinely pay millions of dollars for access to gene fragment databases.[40] Most basic researchers are not in a position to pay such high fees. If these scientists cannot pay for access or use, their research cannot be performed.

This problem is especially likely to occur in the field of human genetic research. Most of the human genome has been sequenced. Analysis of these sequences is beginning. As the number of human genome patents increases, more researchers will be unable to fund required inputs to their basic research.[41]

Negotiating licenses is a costly and time consuming enterprise. For critical research inputs, scientists may be willing and able to transfer their time and resources to licensing activity. In other cases, scientists may forego the research.[42] At best, research may be delayed and scientists may waste time better spent on research.

Similarly, patent holders may restrict access to patented inputs unless a researcher agrees to onerous conditions, such as transferring rights to or paying royalties on

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[39] *See* Andrew Pollack, *Bristol-Myers and Athersys Make Deal on Gene Patents*, N.Y. Times, Jan. 8, 2001.

[40] *See* Rebecca S. Eisenberg & Nelson R. Richard, *Public vs. Proprietary Science: A Fruitful Tension?* 131 Daedalus 89, 94 (2002).

[41] *See id.* at 95.

[42] *See, e.g.*, Rai, *supra* note 38, at 831-32.

sequential inventions. Because these restrictions may deprive researchers of the full range of patent incentives, they may refuse to obtain licenses for the needed inputs.[43] Alternatively, substantial time and resources may be wasted negotiating changes to these restrictive conditions.

These licensing practices already have had substantial adverse effects on basic research.[44] The failure to obtain patent licenses has impeded basic genetic research into autism, HIV, and breast cancer.[45] "A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of [basic] research and product development."[46] A narrow interpretation of the experimental use exception will exacerbate the problem.

III. Like Fair Use in Copyright, the Experimental Use Exception Should Promote Progress.

Both the fair use doctrine in copyright[47] and the experimental use exception in patent, properly defined, work to further the constitutional goal of intellectual

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[43] *See* Rebecca S. Eisenberg, *Reaching Through the Genome*, Federal Reserve Bank of Dallas (April 19, 2002), *available at* www.dallasfed.org/htm/dallas/events/archive/eisenberg.pdf (last visited Jan. 30, 2003).

[44] *See* Eliot Marshall, *A Deluge of Patents Creates Legal Hassles for Research*, 287 Science 255, 255-56 (2000).

[45] *See, e.g.*, Lori B. Andrews, *Biotechnology Symposium: The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2002 Hous. J. Health L. & Policy 65, 87 (2002).

[46] Heller & Eisenberg, *supra* note 18, at 698-99.

[47] 17 U.S.C. § 107.

property law – to "Promote the Progress of Science and the useful Arts."[48] Both are judicially-created doctrines designed to effectuate that goal.[49] The fair use doctrine and the experimental use exception "permit[ ] courts to avoid rigid application of the copyright [and patent] statutes when, on occasion [they] would stifle the very creativity which [the] law is designed to foster."[50]

Courts have continually shaped and refined copyright fair use,[51] ensuring that the doctrine performs its intended function. This Court recently reaffirmed the importance of fair use in balancing the monopoly that a copyright holder enjoys and in assuring the promotion of cultural progress.[52] Copyright law can avoid rigid application only when copyright doctrines respond to changing circumstances and are construed in light the Constitution's purposes.[53]

Like creative expression, basic scientific research builds on past work. A properly defined experimental use exception allows basic research to proceed and to be transferred to applied research and new technologies. The experimental use exception should mirror the broad and flexible functioning of the fair use doctrine. This will

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[48] U.S. Const. Art. I, § 8, cl. 8.

[49] *See Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Folsom v. Marsh*, 9 F. Cas. 342 (C.C.D. Mass. 1841).

[50] *Stewart v. Abend*, 495 U.S. 207, 236 (1990).

[51] *See* David Nimmer, Nimmer on Copyright § 13.05 (2002).

[52] *See Eldred v. Ashcroft*, 123 S. Ct. 769, 788-89 (2003).

[53] *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 432 (1984).

better assure that patent law promotes rather than impedes discovery and invention.

CONCLUSION

This Court now has an opportunity to ensure that the experimental use exception functions to promote progress. The Federal Circuit's narrow definition of the experimental use exception must be reconsidered to preserve and promote basic research, scientific progress, and public health. The Court should grant the writ of *certiorari*.

Respectfully submitted,

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Petitioner,

v.

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Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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QUESTION PRESENTED

Whether the Federal Circuit properly refused to create judicially a *per se* exemption from infringement liability for universities that use the patented inventions of others to conduct research.

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IN THE

Supreme Court of the United States

No. 02-1007

DUKE UNIVERSITY,
Petitioner,

v.

JOHN M. J. MADEY,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR RESPONDENT IN OPPOSITION

INTRODUCTION

The Federal Circuit applied its long-standing precedent concerning the experimental use defense to patent infringement and properly rejected Duke University's argument that it was entitled, as a matter of law, to a *per se* royalty-free use of patented inventions to generate revenue for itself, solely because it is a nonprofit research institution. The court of appeals remanded what it characterized as a "unique patent infringement case" (Pet. App. 3a) – after an interlocutory appeal from a district court decision granting partial summary judgment based on its own overly expansive understanding of Federal Circuit law – so that the factual record could be developed under the proper standard. The Federal Circuit correctly applied well-settled legal principles to require a fact-sensitive determination before making a legal judgment.

Duke's use of the patented inventions was not "experimental use" for scientific study of the inventions themselves. Rather, Dr. Madey offered rebuttal evidence to prove that his laser inventions that are housed at Duke are used for broad-based research – in medicine, nuclear physics, spectroscopy, materials science, and semiconductor technology. As such, Duke's continuing regular use of Dr. Madey's inventions as part of the routine operation of its research facilities advanced Duke's business interests in obtaining tens of millions of dollars in federal grant monies, attracting world-class faculty and students, paying capital and administrative costs at the university, and developing new inventions that Duke intends to patent and license to others. In rejecting Duke's request for a broad-based exemption from the patent laws, the Federal Circuit simply applied well-settled common-law precedent. The court did not produce the cataclysmic change in patent law asserted by petitioner and its *amici*.

Duke offers a welter of policy arguments for revising the patent laws to favor research universities and to limit the rights of inventors and businesses who depend on the protection of the Patent Act. Those suggestions should not be addressed to this Court, but rather to Congress, which has considered similar policy proposals in the past but has not seen fit to adopt them. Supreme Court review of a Federal Circuit decision that is procedurally, factually, and legally correct is not the proper mechanism to establish fundamental changes to the patent system that Congress created by statute under authority of the Constitution. Indeed, the current system serves the public interest well, including dramatically increased earnings in recent years from patent royalties paid to research universities themselves and greater private sector support for expansion of research into new fields.

STATEMENT

Background of Dr. Madey's Invention

As a graduate student in physics at the California Institute of Technology, respondent John M. J. Madey conceived the invention of the free electron laser ("FEL"). As a research scientist in laser physics at Stanford University, he perfected the invention without university or government financing. Prior to that, all lasers had relied on some medium – *e.g.*, ruby, helium-neon gas, or argon ion – and the limitations associated with the medium to achieve the desired results. What Dr. Madey envisioned, and later accomplished, was a new form of laser where the medium is a pure beam of electrons. *See* Arthur L. Schawlow, *Twenty-Five Years of Lasers*, in *Yearbook of Science and the Future* 171, 184-85 (1987). Although he proved the validity of his insight in a demonstration using the Stanford superconducting accelerator, Dr. Madey was unable to obtain any university, government, or other funding to develop his invention. C.A. App. A3344.

Undertaking the personal expense and risk of patenting the invention himself, Dr. Madey then licensed the invention to AT&T, for use by its subsidiary Bell Laboratories to develop its potential. He used the patent royalties from his license agreement and other personal funds to build a prototype FEL. *Id.* at A1417-18. Once it was operational and its capabilities had been demonstrated, Dr. Madey was able to attract research sponsors – primarily the United States Department of Defense. He continued his ground-breaking research, participating in the creation of a major FEL facility in France and stimulating interest in FEL technology on a world-wide basis. With funds provided by the Army's Space and Missile Defense Command through a contract administered by the Los Alamos National Laboratory, Dr. Madey's prototype laser was modified and improved at Stanford and became the "Mark III FEL." *Id.* at A1417-18, A3344-45.

As his Defense Department funding increased, along with the importance of his work to the Nation's defense, Dr. Madey found himself in an unforeseen conflict with Stanford, an institution that had provided him with unparalleled opportunity and which he had served faithfully and enthusiastically. The issue was the amount of "overhead" extracted by Stanford (and not entirely atypical of other major research institutions at the time) from government research grants that Dr. Madey received to support his work. Finding that excessive overhead charges would preclude successful completion of his work with the allotted funds, Dr. Madey objected to Stanford's overhead charges. *Id.* at A1419. The ensuing debate prompted congressional hearings and a national reform of the handling of federal research funds that is honored to the current date.

Dr. Madey's Dispute With Duke

Seeking to pursue his research and fulfill his obligations to his government sponsors, Dr. Madey explored other locations for his research. He was actively recruited by Duke University, where the faculty committee that investigated his credentials noted that virtually everyone interviewed agreed that he was a scientist of Nobel prize caliber. C.A. App. A1880, A1885. Also of significant appeal to Duke was the fact that Dr. Madey enjoyed outside financial support for his research that could not be duplicated by anyone in the field.

Based upon the promises by Duke to allow him to develop and expand his research program, Dr. Madey agreed to transfer his research to Duke, in what was the largest academic transfer of scientific research equipment, personnel, and funding in U.S. history. *Id.* at A136. At Duke, Dr. Madey's success continued. He brought in more than $40 million in research grants and contracts at Duke. *Id.* at A139. The program was so successful that he had been granted a $1 million grant from the W. M. Keck Foundation and an additional $1.3 million from the United States government to expand the FEL laboratory ("FEL Lab") at Duke and its research programs. *Id.* at A140, A1749.

At the same time, funding for nuclear physics – the long-standing mainstay in the field of physics at Duke and elsewhere – was disappearing. Like many post-World War II physics departments, the senior members of the Department of Physics at Duke were predominantly nuclear physicists. Unexpectedly, at least from Dr. Madey's perspective, and without his knowledge, Duke revised the plans for expansion of the FEL Lab in a manner that sought to facilitate the use of the FEL Lab for Duke's own nuclear research projects and at the expense of the government-funded research that Dr. Madey was committed to pursue. *Id.* at A142-45, A1892-907. After Dr. Madey brought these developments to light, the granting agency forced Duke to revise its budget and to provide university funds to cover the additional costs of the laboratory expansion attributable to the nuclear program. *Id.* at A1747-49.

Duke went to extraordinary lengths to impose its will on Dr. Madey, including having him removed as Principal Investigator of his own federal research grant from the Office of Naval Research ("ONR") for medical FEL research (the "MFEL Grant"). *Id.* at A149. Duke purported to justify its action by contending that Dr. Madey's colleagues in the department had lost confidence in his leadership of the research program, because of his protest over the improper diversion of federal funds to benefit Duke's nuclear program. *Id.* at A148-50. He was replaced as Principal Investigator by an academic theorist in the field of nuclear physics with no qualifications in laser physics. *Id.* at A142, A149. Academic scientists and government officials agree that Duke's action in removing Dr. Madey as Principal Investigator on the MFEL Grant is without precedent in American academic history. *See* Affidavit of Dr. George A. Neece, C.A. App. A1448-49; Affidavit of Dr. M. J. Soileau, C.A. App. A1442-43.

Faced with the *de facto* conversion of his research program by Duke, including the Mark III FEL laser that he built and funded initially with his own funds, Dr. Madey was forced to seek a new location for his research. He is

currently a Professor in the Department of Astronomy and Physics at the University of Hawaii, where he is continuing his research. *Id.* at A150. At Duke, Dr. Madey had been awarded a contract by the Defense Department's Office of Nuclear Treaty Organizations for "remote sensing" using the capabilities of the Mark III FEL laser. *Id.* at A1556, A2114. This research is of enormous importance for national defense because it can, among other things, detect underground nuclear detonations on the other side of the world better than any existing technology. Duke had no one else capable of pursing this research, so it was allowed to go unattended while Duke pursued the research that would benefit its own institutional and business objectives. *Id.* at A1556-57, A1672-73, A1676-77.

After Duke removed Dr. Madey as Director of the FEL Lab and Principal Investigator on the MFEL Grant, he gave Duke written notice that it was infringing his patents. Nonetheless, Duke proceeded to make use of the lasers (and the patented inventions) for its own purposes in a multitude of ways, a number of which promise significant financial reward to Duke. *Id.* at A148-50, A1677-78.

It is undisputed that the patents at issue belong to Dr. Madey individually and never belonged to Stanford, Duke, or any other institution. The funds used to obtain the patents and achieve success with the inventions were private funds and not university funds. Although the inventions have yielded little income to Dr. Madey, the laser has been used successfully under license at Vanderbilt University for surgery on an otherwise inoperable brain tumor and was also the centerpiece of the United States' star wars defense plan, for which the government spent approximately $1.5 billion in the 1980s to build a high-powered version of the patented laser at White Sands, New Mexico. *Id.* at A1796, A1870. *See also* Jeff Hecht, *Laser Pioneers* 47 (rev. ed. 1992). The potential uses of FEL technology continue to multiply, including applications in spectroscopy, materials science, and semiconductor technology that have great commercial promise.

District Court Proceedings

In 1997, Dr. Madey filed suit against Duke University for, *inter alia*,[1] infringement of his two patents. C.A. App. A135. The first (U.S. Patent No. 4,641,103 ("the '103 patent")) is for a microwave electron gun that is used as an electron source for FELs and for other purposes. *Id.* at A97-107, A151-52. The second (U.S. Patent No. 5,130,994 ("the '994 patent")) is for the process or capacity of the Mark III FEL commonly referred to as "phase-locking." *Id.* at A110-30, A154-55.

The district court issued two rulings that became the subject of the appeal to the Federal Circuit. First, pursuant to Federal Rule of Civil Procedure 12(b)(1), the court partially dismissed for lack of jurisdiction Dr. Madey's claim for infringement by Duke of the '103 patent. Pet. App. 66a-70a, 95a-96a. The court assumed that federal funding of research in the FEL Lab through a grant from the ONR established, as a matter of law, that any uses of the patents for activities funded under the MFEL Grant were uses "for the United States" pursuant to 28 U.S.C. § 1498(a), which provides for jurisdiction in the U.S. Court of Federal Claims for a claim of patent infringement when the invention is "used or manufactured by or for the United States without license of the owner thereof." *See* Pet. App. 66a-67a. Based on those assumptions, the court concluded that it lacked jurisdiction to hear the portion of Dr. Madey's patent infringement claim that related to activities funded under the MFEL Grant. *Id.* at 67a, 69a-70a.

Second, the district court granted summary judgment to Duke on the remaining patent infringement claims on the

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[1] The other claims before the district court stemmed from Duke's actions in removing Dr. Madey from control over his research program at Duke, and include claims for patent infringement, breach of contract, conversion of personal property, misappropriation of business opportunities, and constructive fraud. C.A. App. A133-64. Only the patent infringement claims were before the Federal Circuit on appeal. The district court's summary of Dr. Madey's various legal claims is at Pet. App. 32a-37a, 58a-61a.

ground that all of Duke's uses of the patents are exempt from infringement liability under the experimental use defense. *Id.* at 31a-54a. The court opined that, for Dr. Madey "to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue 'solely for an experimental or other non-profit purpose.' More specifically, [Dr. Madey] must sufficiently establish that [Duke's] use of the patent had 'definite, cognizable, and not insubstantial commercial purposes.'" *Id.* at 41a (quoting 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000), and *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), respectively) (citation omitted). In that manner, the court shifted the burden of proof to Dr. Madey to disprove Duke's defense to a claim of infringement. As a substantive matter, the court defined the experimental use doctrine as applicable only when the alleged infringer is conducting experiments "with commercial intent." *Id.* at 41a, 44a. The court credited Duke's assertions that its uses were "to teach, research, and expand knowledge," *id.* at 43a, while rejecting Dr. Madey's arguments and evidence that Duke's broader uses of Dr. Madey's patents exceeded the proper scope of the experimental use defense. "Without more concrete evidence to rebut [Duke's] stated purpose with respect to its research in the FEL Lab, [Dr. Madey] has failed to meet [his] burden of establishing patent infringement by a preponderance of the evidence." *Id.* at 45a. The court also declined to exercise supplemental jurisdiction over Dr. Madey's state law claims and, because the patent claims were the basis for federal jurisdiction, dismissed the state law claims without prejudice. *Id.* at 53a-54a, 55a-56a.

The Federal Circuit Decision

The Federal Circuit reversed in relevant part. Pet. App. 1a-30a. First, on the jurisdictional ruling, the court of appeals reversed the dismissal for lack of jurisdiction on the '103 patent claim and remanded the issue to the district court because the evidence in the record was insufficient to show "the scope of the government's rights" or how "the

rights granted to the government encompass Duke's use [of the patented inventions]." *Id.* at 29a. Duke does not seek Supreme Court review of that portion of the Federal Circuit's decision.

Second, on the experimental use defense on which the district court had granted summary judgment for Duke, the Federal Circuit reversed. The court of appeals agreed with Dr. Madey that the district court had committed three errors with respect to the experimental use defense: (1) the district court improperly imposed the burden of proof on Dr. Madey, as plaintiff, rather than on Duke, as the party moving for summary judgment and as the party asserting a defense, *id.* at 21a, 22a-23a; (2) the district court had "applied an overly broad version of the very narrow experimental use defense inconsistent with our precedent," *id.* at 21a, 24a-26a; and (3) the district court had relied on "overly general" evidence that was "not indicative of the specific propositions and findings required by the experimental use defense," *id.* at 21a.

The Federal Circuit explained that the test for application of the experimental use defense for well over 100 years had been whether or not the use was "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a. Noting that use of Dr. Madey's patents furthered Duke's legitimate business interests and that Duke "is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream," *id.* at 26a n.7, the court of appeals remanded the case to the district court for further proceedings.

REASONS FOR DENYING THE PETITION

The Federal Circuit applied well-settled precedent in rejecting Duke's assertion that universities are entitled to a *per se* rule exonerating them from patent infringement claims when their employees conduct experiments. In remanding for further factual development and trial on the merits, the court's interlocutory judgment was faithful to the narrow circumstances in which the judicially created experimental use defense has been applied to relieve an

infringer of a patent holder's congressionally created statutory patent protection. Duke's assertion that the Federal Circuit's ruling will "chill" university research is exaggerated and, in any event, more appropriately directed to Congress rather than this Court.

I. THE FEDERAL CIRCUIT'S DECISION RESTATES WELL-SETTLED LAW AND DOES NOT ALTER THE AVAILABILITY OF THE EXPERIMENTAL USE DEFENSE TO NONPROFIT RESEARCH INSTITUTIONS

The Patent Act does not contain a general exemption from patent infringement liability for research universities or other research organizations. Nothing in the language of the Patent Act allows for distinctions between classes of users in weighing whether or not unauthorized use constitutes infringement of a patent. *See* 35 U.S.C. § 271(a) ("*[W]hoever* without authority . . . uses . . . any patented invention . . . infringes the patent.") (emphasis added). When the Federal Circuit rejected Duke's efforts to transform the narrow experimental use defense into a *per se* general exemption allowing free use of patented inventions by nonprofit organizations, it did so on the basis of settled law defining the scope of the experimental use defense. That defense, when properly defined and factually justified, remains equally available to all users – commercial and nonprofit alike.

A. The Origins Of The Experimental Use Doctrine Established A Limited Exemption From Infringement Liability For Experimentation On The Patented Device Itself

The earliest expressions of what has been called the experimental use exception, by Justice Story in *dicta*, identify scientific study of the invention itself for the advancement of knowledge as the activity to be protected:

> Use or construction "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects,"

Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

"[F]or the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification." *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

Decades later, that explanation for the experimental use exception had not changed, as a leading circuit decision stated that "an experiment *with a patented article* for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee." *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (emphasis added).[2]

Those judicial descriptions of the doctrine were synthesized later in the nineteenth century by a treatise writer on patents, Professor William Robinson, who articulated the underlying principles behind protecting a patent and permitting a narrow exception for experiments conducted on the patented device: "The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others," subject to a limited exception for certain types of experiments:

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[2] The term "experimental use" is also used in a different context in disputes regarding patentability of inventions. Section 102(b) of the Patent Act establishes a bar to patentability for inventions that have been in public use for more than one year. In this context, an experimental use doctrine evolved in recognition of the public benefits that would result from allowing inventors to experiment with their inventions before applying for patent protection. One commentator uses the term "inventor experimental use" for this doctrine and the term "third-party experimental use" in the infringement context. *See* Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 Nw. U. L. Rev. 667, 667 (1997). The legal standards that have developed for the two uses of the term thus address the different concerns that exist for patentability and infringement. *See* 2 *Chisum on Patents* § 6.02[7]; *see also City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. (7 Otto) 126 (1877) (addressing "experimental use" in the context of patentability).

> [W]here it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.

3 William C. Robinson, *The Law of Patents for Useful Inventions* § 898, at 55-56 (photo. reprint 1972) (1890) (footnote omitted). As Professor Robinson further noted: "[I]f the products of the experiment are . . . used for the convenience of the experimentor, or if the experiments are conducted with a view to adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent." *Id.* at 56, *quoted in Roche Prods.*, 733 F.2d at 862.

B. Modern Applications Of The Experimental Use Defense Have Retained Its Narrow Focus

Modern applications of the experimental use defense have continued to observe those limitations. For example, in *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000) (per curiam), the Federal Circuit explained that it has long construed the experimental use exception "very narrowly." *Id.* at 1349. In that case, the court of appeals rejected an experimental use defense based on the district court's findings that tests were performed "expressly for commercial purposes" to sell the infringer's competing machines to potential customers. *Id.* The court found unpersuasive the infringer's effort "to cloak these tests in the guise of scientific inquiry," because the tests were not conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* (internal quotation marks omitted).

The articulation and application of the experimental use defense in *Embrex* followed logically from the Federal Circuit's decision in *Roche Products*, in which the court rejected an experimental use defense because the use of

patented drug ingredients for development of a competing product was "for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." 733 F.2d at 863. The court was unpersuaded by public policy arguments in favor of an exemption for such activities. *Id.* As the court noted, the experimental use defense originated out of a common-sense notion that *de minimis* uses of a patented device through experimentation on the device itself should not rise to the level of actionable infringements. But "[i]t is no trifle in its economic effect on the parties even if the quantity used is small" when the "unlicensed experiments [are] conducted with a view to the adaption of the patented invention to the experimentor's business." *Id.* Such use "is a violation of the rights of the patentee to exclude others from using his patented invention." *Id.*

The holdings of those Federal Circuit decisions – on which the court below expressly relied – followed on a line of prior cases that had defined the narrow contours of the experimental use defense. *See, e.g., Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 634 (1990) (governmental use "to explore the technical and economic feasibility of controlling and eliminating the hydrogen sulfide emissions" was infringing) (internal quotation marks omitted); *Douglas v. United States*, 181 U.S.P.Q. (BNA) 170, 177 (Ct. Cl. 1974) ("each use [of patented jet engine designs] was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose" and was infringing), *modified on other grounds*, 510 F.2d 364 (Ct. Cl. 1975) (per curiam).

Petitioner erroneously asserts that the Federal Circuit "overrode Congress' legislative judgment . . . by misapplying language from a wholly irrelevant case." Pet. 13 (citing *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976) (per curiam)). That assertion is insupportable, because the experimental use defense has never been enacted or codified in any form by Congress; rather, it has only been a judicially recognized defense to avoid infringement liability in

a narrowly defined circumstance. Petitioner's criticism of the Federal Circuit's invocation of *Pitcairn* also misses the mark, because the Federal Circuit merely cited that case for a widely accepted proposition: that an infringer cannot invoke the experimental use defense for a "use in keeping with the legitimate business of the alleged infringer." Pet. App. 24a. In *Pitcairn*, the court rejected an experimental use defense for governmental tests of helicopters with patented features "for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors," all of which were intended uses that infringed the patents because they were "in keeping with the legitimate business of the using agency." 547 F.2d at 1125-26. *See also Embrex*, 216 F.3d at 1349; *Douglas*, 181 U.S.P.Q. at 177.

C. The Decision Below Consistently Applied Well-Settled Federal Circuit Precedent

The Federal Circuit stressed that it was applying those well-settled precedents to the facts of this case. "Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form." Pet. App. 21a. "[W]e . . . conclude the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*, 216 F.3d at 1349, and in *Roche*, 733 F.2d at 863." *Id.* at 22a (parallel citations omitted). Indeed, the court of appeals determined that the principal flaw of the district court's analysis was its deviation from the binding precedent of *Embrex*, *Roche*, and *Pitcairn*. *Id.* at 25a.

The court of appeals stressed that the district court had erred in not conducting a "detailed analysis of the character, nature and effect of the use." *Id.* "The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a. Because the district court instead had focused on the kind

of institution that Duke is, rather than on the kind of uses to which it was putting Dr. Madey's inventions, the case needed to be remanded for further fact-finding.

The Federal Circuit's determination that a remand was necessary is unassailable, as the proper determination of experimental use – like that of infringement itself – is a question of fact. *Bai v. L&L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). Here, such fact-finding is necessary to confirm whether Duke has made regular use of the patented inventions in the ordinary course of its business by operating the lasers for their intended purpose as light sources used to remove animal tissue, to make precise measurements for standards, to identify substances and their molecular structure, and other functions to which the patents are directed. These uses were not for experimental study of the lasers as such and how they operate, but were routine operations of the lasers for other existing research purposes. These uses include activities designed to enhance Duke's capabilities as a provider of fee-generating medical services, for research funded by federal agencies, for research or product testing for corporate sponsors, for general use in their research by interested faculty members or other researchers authorized by Duke, and for the development of inventions for which Duke intends to obtain its own patents.

Under the principles of well-settled law established by *Embrex*, *Roche*, and *Pitcairn*, Dr. Madey has a right to ascertain at trial whether Duke's uses of the patented inventions go beyond experimental use and to require that Duke prove that the use is not exempt from infringement liability. Duke did not experiment *on* the lasers or their operations; Duke experimented *with* the lasers for its own purposes and benefit. The Federal Circuit's remand to the district court to develop a complete factual record of the character, nature, and effect of Duke's uses of the patented inventions thus constitutes no change in the law governing the experimental use defense by nonprofit universities; it is

simply an application of settled law to the unique factual situation presented. Pet. App. 3a, 25a-26a.

D. Petitioner's Criticisms Of The Federal Circuit's Well-Settled Law Are Unpersuasive

In an effort to make the decision below appear to be an extravagant departure from precedent, rather than merely a fact-bound application of settled law, petitioner makes a number of assertions that do not withstand scrutiny.

First, Duke contends that "the Federal Circuit's formulation of the exception renders it an empty shell, unavailable to the very entities the exemption was intended to cover." Pet. 5. As a preliminary matter, the phrase "the very entities the exemption was intended to cover" underscores petitioner's misguided belief that the experimental use defense is an "exemption" from patent infringement liability that has been conferred on certain "entities," namely, research universities. Duke offers no authority for its sweeping assertion, which is completely antithetical to the development of the experimental use doctrine. In each of the early references to experimental use cited by petitioner (Pet. 9), the researcher involved was a solitary, philosophically minded individual, not an "entity," and what the court or commentator in each such case deemed worthy of protection from the reach of the Patent Act is philosophical inquiry with "the sole effect being of an intellectual character in the promotion of the [user's] knowledge or the relaxation afforded to his mind." Pet. 10-11 (quoting 3 Robinson, *Law of Patents* § 898, at 55-56).

Petitioner can point to no judicial authority that has ever accepted its extraordinary and over-broad assertion that the experimental use defense gives researchers in universities carte blanche to infringe on patents. Justice Story surely did not have in mind the transmogrification of a limited exception that inoculated a researcher's individual curiosity into a *per se* rule allowing a multi-billion dollar research institution to enjoy royalty-free use of inventions

created solely by the ingenuity and perseverance of an individual inventor.

Second, petitioner's contention that the Federal Circuit's decision deprives nonprofit organizations, but *not* commercial users, of the benefit of the experimental use doctrine is incorrect. The court of appeals rejected the idea that the "character, nature and effect of the use" of the patented invention could be determined by the tax exempt status *vel non* of the user. Pet. App. 25a. As the court below explained, the focus is on the "use" and whether it can truly be regarded as "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a. A major manufacturing concern and a nonprofit university alike that limit exploration of a patented invention to "ascertaining the sufficiency of the machine to produce its described effects," *Whittemore*, 29 F. Cas. at 1121, will be entitled to rely on the experimental use defense. *See also Sawin*, 21 F. Cas. at 555 (experimentation exempt from infringement claim if "for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification"). However, use of the patented article as disclosed in the patent to develop other valuable processes or products *is* infringement, even if the infringing activity is conducted by a "nonprofit" research institution. Under the Patent Act, any use of a patented invention for such other purposes without authority would constitute infringement. The sole pertinent issue is the nature of the "use" and whether it somehow qualifies as "philosophical inquiry" rather than the actual "use" to which the patent was directed. In this case, the Federal Circuit ordered a remand to determine whether Duke used the patented inventions regularly as they were intended to be used, not to verify their utility, but rather to obtain the benefits of the patented use.

Third, there is no merit to Duke's contention (Pet. 5-6, 13) that the court below improperly rested its decision on *Pitcairn*'s firmly established legal principles. The Federal Circuit's paraphrase of language from *Pitcairn* that "use in

keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense" is both accurate and apposite. Pet. App. 24a. Duke was not studying the lasers to ascertain how they functioned; Duke was using the function of the patented invention for its own purposes as part of a major research facility designed, among other things, to facilitate technology transfer to the private sector and to advance the creation of university-industry partnerships in developing commercial applications from the scientific discoveries in the FEL Lab. In this fashion, and in its solicitation of research funds, government contracts, and other revenue-generating activities, Duke is a direct economic competitor with Dr. Madey and his FEL research program.

Under these circumstances, and given the district court's misunderstanding of the proper scope of the experimental use defense, the Federal Circuit properly concluded that the disputed facts regarding the "character, nature and effect" (*id.* at 25a) of Duke's use of the patented inventions needed to be fully developed in further proceedings before the district court.

II. THE PUBLIC INTEREST IN THE ADVANCEMENT OF KNOWLEDGE IS BETTER SERVED BY EXISTING LAW THAN BY JUDICIAL EXPANSION OF THE EXPERIMENTAL USE DEFENSE

There is no merit to petitioner's hyperbolic assertion that "the Federal Circuit's opinion threatens substantial delay, further commercialization of non-profit research, and even the complete cessation of certain research projects." Pet. 19. Nonprofit research universities continue to enjoy the benefits of the experimental use defense for all activities that are properly classified as "experimental use," which includes verification and replication of the results of the inventor, as well as study of the invention itself and how it works for purposes of scientific understanding and advancement of knowledge. Only when universities go beyond such activities – without obtaining a license or otherwise

respecting a patent holder's rights – does patent infringement become an issue.

A. Basic Research Is Unaffected By The Federal Circuit's Experimental Use Doctrine

It is untrue that basic scientific research will be impeded unless universities are given free access to increasingly specialized bits of knowledge that may be patented. *See* Pet. 16-18. A recent survey by academic researchers, who conducted extensive interviews with university researchers and technology transfer officers, attorneys in the field of intellectual property, government and trade association personnel, and representatives of the private sector, revealed that "almost none of our respondents reported worthwhile projects being stopped because of issues of access to [intellectual property] rights to research tools." Instead, the survey concluded, "[o]ur interviews reveal that university and industrial researchers have adopted 'working solutions' that allow their research to proceed."[3]

Indeed, Duke, like other major universities, is in the forefront of making its discoveries available to the public for both commercial and non-commercial purposes – with an active program of technology licensing to the private sector, extensive corporate sponsorships for research, and participation in mutually beneficial collaborations with industry. While none of this activity is in any way improper, it does serve to demonstrate how far removed Duke's interests are from the disinterested "philosophical experiment" of individual scientists interested only in the advancement of learning that gave rise to the experimental use defense. Even if it may once have made sense to presume that the interest of a major private university in scientific advancement was synonymous with the public interest, that is no

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[3] John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, Science, Feb. 14, 2003, at 1021 (excerpted from John P. Walsh, Ashish Arora & Wesley M. Cohen, *Patents in the Knowledge-Based Economy* (W.M. Cohen & S. Merrill eds., National Academy Press, Washington, D.C., publication pending)).

longer the case. *See* Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 High Tech. L.J. 369, 380-81 (1992) ("the gap between basic research and commercial interest has 'dramatically narrowed'"). Seeking financial resources dominates academia as much as it does the private sector. Indeed, the line between them is greatly blurred and cannot provide a principled basis for a legal rule as to when infringement of inventions is permitted.

As a result of Duke's extensive activities in developing new technologies and ensuring that its own inventions receive the protections of the patent laws, it has an extensive cadre of administrators and numerous legal advisers, from in-house counsel to prominent law firms, guiding Duke on how to maximize the financial rewards from its research. In 2001, universities earned $1.26 billion from technology licensing. *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289, 300 n.60 (Winter 2003), *available at* http://www.law.upenn.edu/fac/akrai/lcp.update.922.doc. Those same resources surely can be applied to developing lawful ways of using the patented devices of other inventors rather than simply expropriating them.

B. Duke Seeks To Impose A Double Standard That Harms Entrepreneurial Efforts While Giving Universities A Windfall On The Use Of Patented Inventions

Apart from the substantial question of why a well-endowed and successful research institution should be entitled to free use of inventions that competing small businesses or individual users must negotiate for, and pay for, in the marketplace, there is no reason to assume that such government-compelled largesse will actually benefit the public, as Duke incorrectly asserts (Pet. 18-25). Major universities have become substantial competitors in the battle to achieve dominance and financial success in new scientific markets. That development may be a positive one, but it should not be confused with an altruistic search for the

truth that needs to be subsidized by America's inventors and entrepreneurs. Nothing in petitioner's view of the law obligates Duke to share freely with others the results of the research that *it* is undertaking with use of inventions patented by others. Duke, like other research institutions, will itself patent and control any discoveries that it makes through use of Dr. Madey's inventions for Duke's own private benefit.

A significant portion of the major advances in developing high-tech products and services has been made by relatively small companies. To attract the capital necessary to make such ventures successful, entrepreneurs need the protection provided by the Patent Act to keep powerful competitors, like Duke and other major research institutions, from simply appropriating these entrepreneurs' inventions for their own purposes. Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 381, 391, 396-97. Indeed, substantial policy concerns militate against granting academic departments the power to control the rate of progress in the advancement of new fields of scientific discovery. Increased support for basic scientific research and academic-commercial collaboration to deliver the promise of those discoveries to the world need not be financed by the expropriation of small inventors' patent rights. Commentators have noted the dangers in disrupting the prevailing patent regime:

> Changes in the patent laws that . . . exempt research activities from infringement liability could have a significant effect on the ability of these firms to raise funds for research. Given that overall private investment in biomedical R&D today exceeds public funding, the strong belief of private sector investors that patents are essential to their profit expectations urges caution in changing the underlying legal rules that support these investments.

Rai & Eisenberg, *Bayh-Dole Reform*, 66 Law & Contemp. Probs. at 299.

The Federal Circuit's decision in this case did not cause the growing trend toward commercialization of academic research. Nor would a contrary result in this case have any noticeable impact on the increasing desire of universities and commercial interests to collaborate in research endeavors. The forces driving that convergence, in both the academic and the private sector, remain powerful. On the academic side, operating costs for universities have increased with expanding numbers of scientists attracted to new and diverse fields, while government spending to support university research has not increased. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 379 n.57, 380. *See also* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 33 & n.166 (2001). At the same time, private industry wants to avoid investing the capital and other resources needed to maintain the infrastructure for broad scientific research, and yet private firms are increasingly vulnerable to scientific advances by competitors that may be financially devastating. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 381. The trend toward collaboration undoubtedly will continue, particularly if budget constraints force reduced federal spending on scientific research.

C. Duke's Contention That The Federal Circuit Decision Upsets Settled Expectations Has No Merit

Duke complains that the Federal Circuit's adherence to existing settled limits on the scope of the experimental use defense deprives university researchers of the "universal assumption" (Pet. 18) that they were exempt from the patent laws, thereby producing uncertainty and inadvertent patent violations. That argument not only is at odds with the facts of this case – Duke is knowledgeable of patent obligations in general and was given advance written notice of its infringing activities – but also grossly overstates the impact of the Federal Circuit's ruling regarding Duke's

actions. The experimental use defense is a common law doctrine derived from existing court decisions. No reasonable reliance can be placed on that doctrine by any interested party without careful analysis of the facts and circumstances under which the person plans to make use of a patented invention. The obligation to make an appropriate evaluation of the "character, nature and effect" (Pet. App. 25a) of any proposed use of a patented invention predated the decision in this case. It remains possible for university researchers to enjoy the benefit of the experimental use defense so long as they confine their activities to strictly experimental use in the forms recognized by the Federal Circuit and other courts. On the other hand, as universities pursue more and more research directed at achieving commercial success rather than satisfying philosophical curiosity, they will be obligated to honor the requirements of the patent laws and may therefore be unable to establish that they qualify for the experimental use defense. That obligation derives from the change in the nature and objectives of the universities' research and not from any change in the law. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 377 ("It is through the universities' own attempts to monopolize research results and collaborate with the commercial sector that they have potentially lost claim to the experimental use exception.").

Whatever uncertainty exists in the current system results from the variability of fact-intensive inquiries, as contrasted with *per se* bright-line rules. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002) (rejecting a bright-line rule for the application of prosecution history estoppel to the doctrine of equivalents). In any event, the prevailing incentives (including extra-legal rewards of scientific and professional recognition) have been sufficient to fuel a boom in scientific research and a flood of patents by research universities. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 400 & nn.159-161; Mueller, *No "Dilettante Affair,"* 76 Wash. L. Rev. at 34-35 & n.177. Petitioner acknowledges the unprec-

edented advances flowing from the patented Cohen-Boyer discoveries in gene cloning. *See* Pet. 18. The widespread use of those discoveries was made possible by a far-sighted licensing policy adopted by the inventors. Duke worries that other inventors may not follow the Cohen-Boyer model and may adopt more restrictive licensing policies that would require it to engage in negotiations for patent rights. Duke suggests that it should not be required to make such accommodations in planning its research and that it and other research universities may be unable to handle the demands of marketplace negotiations for patent rights related to their research operations. Pet. 18-19. Experience to date indicates that Duke is wrong and that patent holders will indeed want to participate in additional scientific explorations that may yield vastly increased demand for their innovations.[4] What is not clear from Duke's argument is how the public interest would be served by shifting the power to decide what use is made of ground-breaking inventions away from the scientists who created them and into the hands of the technology managers running the highly competitive research operations at major universities.

Duke's real complaint is an objection to the patent system itself: "The possibility that the patent system could stifle or even stymie the progress of biotechnology and other important fields of research is both real and profound." Pet. 20. Duke essentially opposes the statutory monopoly given to inventors by Congress pursuant to the Constitution, on the grounds that it may limit useful research by others during the period of patent protection. Yet this is precisely the function exclusive patent rights were intended to perform:

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[4] A recent study estimates that, in 1995, licenses of patented inventions by universities produced $4.6 billion in investments and created 27,000 jobs in research and development toward commercialization of those university research results. *See* Peter B. Kramer, *et al.*, *Induced Investments and Jobs Produced by Exclusive Patent Licenses – a Confirmatory Study* (1997), *available at* http://www.autm.net/pubs/journal/97/5-97.html.

> A patent is a device to prevent the diffusion of new methods before the original investor has recovered profit adequate to induce the requisite investment. The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse. . . . Since it is rooted in contradiction, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in particular instances, impeding progress unnecessarily even if its general effect is favorable on balance.

Joan Robinson, *The Accumulation of Capital* 87 (1956), *quoted in* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 409-10 (ellipsis in original).

To the extent patent law is intended to promote independent philosophical inquiry by thoughtful scientists, as the experimental use doctrine has traditionally been understood, it makes no sense to deprive the individual inventor of the benefits of his invention for the enrichment of university bureaucracies. In this case, Duke ignored the public interest and its obligations to the inventor and faculty member who made the university's success in this field possible. The Federal Circuit remanded the case for further proceedings to determine the rights of the parties based on the existing contours of a judicial doctrine that has been consistently applied since its original articulation nearly two hundred years ago. While Duke's desire to rewrite the law so that it may be exonerated from liability for its infringement is understandable, there is no public interest justification for such judicial intervention.

In any event, Duke's numerous policy arguments are better addressed to Congress, which can define by statute in the Patent Act the contours of any experimental use exception that is deemed both desirable for policy reasons and consistent with the Constitution's protections on a patent holder's rights. *See Infigen, Inc. v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967, 981 (W.D. Wis. 1999) ("[I]t is up to Congress to decide whether there should be an infringe-

ment exemption for university-based research laboratories. So far, Congress has not seen fit to grant one. *See, e.g.*, Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, [101st] Cong. (1990), which was never passed but which, among other things, proposed exemptions from infringement liability for university research."). This Court should not accept petitioner's invitation to engage in a legislative function by engrafting onto the Patent Act an expansive exemption that departs from well-settled patent doctrine.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M. J. MADEY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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INTRODUCTION

Beginning with the statement of the question presented, and continuing throughout the introduction, statement of facts, and argument, the brief in opposition gets this case backwards. Dr. Madey claims that Duke asked for a *per se* experimental use exemption for research universities and that the Federal Circuit limited the exemption to its historic scope. In fact, Duke sought an application of the experimental use exemption consistent with tradition and precedent, pursuant to which the exemption is available when academic scientific research is directed toward noncommercial objectives. The Federal Circuit, however, in a radical departure from past doctrine, announced a new *per se* rule denying the exemption to any and all academic scientific research because, the court explained, such research, even when purely noncommercial in nature, furthers the sponsoring university's "legitimate business [of] educating and enlightening students and faculty." App. at 25a. The question presented by this case is whether ***this*** *per se* rule, together with its peculiar rationale, should constitute the new law of the land. This question is of manifest importance and warrants immediate plenary review.

ARGUMENT

I. DR. MADEY MISREPRESENTS DUKE'S ARGUMENT AND THE BASIS OF THE FEDERAL CIRCUIT'S DECISION

According to Dr. Madey, "the Federal Circuit rejected Duke's efforts to transform the narrow experimental use defense into a *per se* general exemption allowing free use of patented inventions by nonprofit organizations" based on

"settled law defining the scope of the experimental use defense." Brief for Respondent in Opposition ("Resp. Br.") at 10. Dr. Madey is wrong about Duke's argument and the basis of the Federal Circuit's decision.

First, Duke is not arguing that nonprofit organizations are *per se* exempt from patent infringement and it is not advocating a "double standard." Resp. Br. at 20. Indeed, Dr. Madey has it backwards. Duke has argued throughout this litigation that research universities, like commercial enterprises, should be able to make noncommercial, experimental use of patents. In rejecting this argument, the Federal Circuit did not "stress[ ] that the district court had erred in not conducting a 'detailed analysis of the character, nature and effect of the uses.'" Resp. Br. at 14 (misquoting language that the Federal Circuit used in criticizing the decision in *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935)). Instead, it adopted a *per se* rule that research universities are precluded from making noncommercial experimental use of patents "regardless of commercial implications" because such use furthers their "legitimate business objectives [of] educating and enlightening students and faculty." App. at 25a.

Second, the Federal Circuit did not decide this case on the basis of "settled law defining the scope of the experimental use defense." Resp. Br. at 10. From its inception, the experimental use exception to patent infringement has turned on whether the use was commercial in nature. *See Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (patent infringement requires "an intent to use for profit"). That view prevailed for almost two centuries and, indeed, was embraced by the Federal Circuit in recent years. *See Embrex, Inc. v. Service Eng'g*

Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) (experimental use exception does not protect research performed "expressly for commercial purposes"); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (tests that have "definite, cognizable, and not insubstantial commercial purposes" not allowed under the experimental use exception). In this case, however, the Federal Circuit radically departed from this settled law, which Congress implicitly adopted in the 1952 Patent Act.

The Court's rationale for departing from the settled law turns the experimental use exception on its head. The experimental use exception always has permitted uses that were educational or enlightening. *See Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); *Sawin*, 21 F. Cas. 554. After the Federal Circuit's decision, however, entities that are dedicated to educating or enlightening – unlike avowedly commercial enterprises – are prohibited from making any experimental use of a patent. Thus, not only does the Federal Circuit's decision upset "the settled expectations of the inventing community," *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1841 (2002) (citation omitted), it does so for precisely the wrong reasons.

Consistent with the usual practice of appellate courts, the Federal Circuit did not enter summary judgment for Dr. Madey (the non-moving party) on the experimental use exception but instead remanded the case to the district court for further proceedings. *See* 10A Charles Alan Wright *et al.*, Federal Practice and Procedure: Civil § 2716, at 294 (3d ed. 1998). That remand, however, is an empty shell with respect to the experimental use exception. Contrary to Dr. Madey's suggestion, the Federal Circuit did not remand the case

"to develop a complete factual record of the character, nature, and effect of Duke's uses of the patented inventions." Resp. Br. at 15. It announced a new legal standard and directed the district court "to significantly narrow and limit its conception of the experimental use defense" accordingly. App. at 26a. The Federal Circuit, moreover, performed the dispositive analysis for the district court. According to the Federal Circuit, "Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives." *Id.* (footnote omitted). In particular, according to the Federal Circuit, the legitimate business of Duke includes "educating and enlightening students and faculty" and "increas[ing] the status of the institution and lur[ing] lucrative research grants, students and faculty." App. at 25a. And, according to the Federal Circuit, because the University's research projects "unmistakably further the institution's legitimate business objectives," it is prohibited from relying on the experimental use exception for research projects "regardless of commercial implications." *Id.* The Federal Circuit's decision forecloses Duke from relying on the experimental use exception on remand in this case and it effectively forecloses any other research university from relying on the exception in any other case involving the university's research projects.

II. MADEY'S PROPOSED EXPERIMENTAL USE STANDARD DOES NOT SUPPORT THE DENIAL OF CERTIORARI

Dr. Madey's own unease with the Federal Circuit's test is revealed by his unwillingness to defend it. Madey barely mentions the Court of Appeals' "legitimate business" test other than to argue that *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976), was properly decided. Dr. Madey instead

proposes a different, extremely narrow experimental use exception that would be applicable to *both* non-profit research institutions and commercial enterprises. In Dr. Madey's view, the "experimental use" exception is limited to "verification and replication of the results of the inventor, as well as the invention itself and how it works for purposes of scientific understanding and advancement of knowledge." Resp. Br. at 18. Under Dr. Madey's standard, "[a] major manufacturing concern and a nonprofit university alike that limit exploration of a patented invention to 'ascertaining the sufficiency of the machine to produce its described effects,' will be entitled to rely on the experimental use defense." Resp. Br. at 17 (citations omitted).

In advocating a third test – one that falls between the commercial-noncommercial distinction of the historical test and the *per se* prohibition announced by the Court of Appeals – Dr. Madey confirms the importance of having the Supreme Court address the contours of the experimental use exception to patent infringement. Dr. Madey tries to suggest that the Federal Circuit embraced this standard by baldly proclaiming that "the Federal Circuit ordered a remand to determine whether Duke used the patented inventions regularly as they were intended to be used, not to verify their utility, but rather to obtain the benefits of the patented use." *Id.* Nothing in the Federal Circuit's opinion supports this assertion. Instead, the Federal Circuit concluded that Duke's status as a research university precluded it from relying on the experimental use exception altogether.

In any event, the case law has never recognized the distinction advocated by Dr. Madey. The experimental use exception always has applied *both* to uses "for the purpose of ascertaining the sufficiency of the machine to produce its

desired effects" (Dr. Madey's position) *and* uses for "philosophical experiments." *Whittemore v. Cutter*, 29 F. Cas. at 1121. Dr. Madey ignores the inconvenient "philosophical experiments" prong of this test. In early nineteenth century parlance, "philosophical" meant "[p]ertaining to, or used in the study of, natural philosophy, or some branch of physical science; physical, scientific." The Compact Oxford English Dictionary 687 (2d ed. 1991); *see also* Webster's Third New International Dictionary 1698 (1986) ("philosophical" meant "characterized by learning or the spirit of inquiry: scholarly" and "of or relating to the physical sciences"). The experimental use exception, therefore, always has been understood to apply to uses of a patent in scientific experiments, and the determinative factor always has been whether the uses were commercial in nature. *See Sawin*, 21 F. Cas. at 555. It has not, as Dr. Madey argues, applied only to uses of patented inventions to determine whether they work.

III. DR. MADEY CANNOT DISPUTE THE SIGNIFICANCE OF THE FEDERAL CIRCUIT'S DECISION

Contrary to Dr. Madey's suggestion, Duke does not "oppose[ ] the statutory monopoly given to inventors by Congress pursuant to the Constitution." Resp. Br. at 24. It agrees with Dr. Madey that, before this case, patent law struck an appropriate balance between protecting patent rights and permitting important noncommercial research to proceed. It disagrees with Dr. Madey, however, over whether the Federal Circuit's decision has upset that delicate balance with adverse consequences for scientific progress in this country. Dr. Madey's argument that research will not be impaired is based on the mistaken premise that the Federal Circuit's

decision did not change the law pertaining to the availability of the experimental use exception to noncommercial research by universities. Because Dr. Madey's premise is wrong, his conclusion is equally invalid.

Not only is Dr. Madey wrong about the law, he is wrong about the perception within the academic and scientific communities about what the law permitted. Patent law historically has not unduly inhibited academic research because parties universally have understood that it permitted researchers to conduct non-commercial experiments without the threat of possible infringement. The Federal Circuit's opinion has changed that understanding. Indeed, an authority cited by Dr. Madey concludes that "the effective elimination of the research exemption by the recent Circuit Court *Madey v. Duke University* decision may undermine the informal exemption that, as our interviews suggest, is important for open science." John P. Walsh *et al.*, *Working Through the Patent Problem*, 299 Science 1021, 1021 (Feb. 14, 2003) (footnote omitted). And, as the *amici* have confirmed, "[t]he Federal Circuit's opinion in this case will have a very damaging chilling effect on all university-based scientific research." Brief for Association of American Medical Colleges, *et al.*, as *Amici Curiae* in Support of Petitioner, at 13.

CONCLUSION

The Court should grant the petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

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In the Supreme Court of the United States

DUKE UNIVERSITY, PETITIONER

v.

JOHN M. J. MADEY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether petitioner is entitled to summary judgment on respondent's claim of patent infringement under 35 U.S.C. 271(a), on the ground that petitioner's unauthorized use of respondent's patented inventions is protected under the common law defense of experimental use.

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In the Supreme Court of the United States

No. 02-1007

DUKE UNIVERSITY, PETITIONER

v.

JOHN M. J. MADEY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTRODUCTION

This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. The position of the United States is that the petition for certiorari should be denied. The court of appeals' decision does not directly conflict with prior precedent discussing the boundaries of the common law experimental use defense to patent infringement. To the extent that petitioner reads the decision to break new ground, the interlocutory posture of this case will afford the lower courts with an opportunity on remand to clarify the scope of the experimental use defense after further factual development concerning the allegedly infringing uses of respondent's patented inventions. The policy concerns raised by petitioner and its amici may be alleviated by such further clarification on remand and, in any event, may be better suited for legislative rather than judicial consideration.

STATEMENT

1. Respondent, an acclaimed physicist, invented the free electron laser (FEL) in the 1980s. During that time, respondent was a tenured professor at Stanford University, where he obtained patents for the two inventions that are at issue in this case. The first patent (the '103 patent) is for a microwave electron gun that is used as an electron source for FELs. The second patent (the '994 patent) is for an FEL oscillator. Pet. App. 2a-3a.

In 1988, respondent accepted an offer for a tenured position in petitioner's physics department. Shortly thereafter, he moved his FEL research laboratory from Stanford to a new laboratory facility on petitioner's campus. The laboratory contains two FELs, known as the "Mark III FEL" and the "Storage Ring FEL," which incorporate the inventions covered by the '103 and '994 patents. Pet. App. 2a, 4a. Respondent served as the director of petitioner's FEL laboratory until 1997, when a dispute led petitioner to remove respondent from that post. Respondent resigned from petitioner's faculty and has continued his academic and research activities at the University of Hawaii. *Id.* at 3a.

After respondent's departure, petitioner has continued to use the Mark III FEL and the Storage Ring FEL. Pet. App. 3a. Petitioner asserts that the equipment is being used for academic purposes, including instruction and research, and not commercial purposes. Pet. 3. The record does not indicate the specific uses that petitioner has made of the FEL equipment, but it is undisputed that petitioner has not obtained a license from respondent to use the inventions covered by the '103 and '994 patents.[1]

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[1] Research that led to respondent's development of the FEL and the patents at issue was funded in part by the federal government. Although not reflected in the record of the instant dispute, the Department of Energy has informed petitioner that the Mark III FEL and related equipment that was part of respondent's FEL laboratory and remains in

2. Respondent brought suit against petitioner for patent infringement and various other federal and state law claims. Respondent claimed, *inter alia*, that petitioner infringed the '103 and '994 patents by using the inventions (as incorporated in the Mark III FEL and the Storage Ring FEL) without his permission. Respondent's infringement claim is predicated on Section 271(a) of the Patent Act, which provides in relevant part that "whoever without authority makes, *uses*, offers to sell, or sells any patented invention * * * during the term of the patent therefor, infringes the patent." 35 U.S.C. 271(a) (emphasis added).

3. The district court entered summary judgment for petitioner on respondent's patent infringement claim. Pet. App. 31a-56a. The court explained that, although unauthorized use of a patented invention is proscribed by the Patent Act, "for well over a century, United States 'patent jurisprudence has paid homage to . . . an exception from infringement liability for . . . unauthorized uses of patented inventions[,]' where the uses were solely for research, academic, or experimental purposes." *Id.* at 40a. The court further stated that the common law experimental use "defense remains viable and may be asserted in those cases in which the allegedly infringing use of the patent is made for experimental, nonprofit purposes only." *Ibid.*

The district court concluded that the experimental use defense is a complete answer to respondent's patent infringement claim. Pet. App. 39a-46a. The court explained that respondent had the burden of proving that petitioner "has *not* used the equipment at issue 'solely for an experimental or other non-profit purpose'" and that petitioner's use of the equipment "had definite, cognizable, and not insubstantial

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petitioner's custody is the property of the United States government. The Department has requested petitioner to transfer the equipment to the University of Hawaii, in order to carry out a federal grant project supporting important domestic security related research.

commercial purposes." *Id.* at 41a (quotations omitted; emphasis added). The court found that respondent failed to meet that burden, explaining that petitioner's "primary purpose is to teach, research, and expand knowledge" and that respondent's "mere speculation that [petitioner] intends, in this case, to stray from [that] general policy * * * is insufficient to create a genuine issue of material fact." *Id.* at 43a.

4. The Federal Circuit reversed in pertinent part and remanded. Pet. App. 1a-30a. The Federal Circuit agreed that the "judicially created experimental use defense" remains available, *id.* at 21a, but it concluded that the district court erred in applying that defense and, "consequently, incorrectly found that there was no genuine issue of material fact upon which [respondent] could prevail," *id.* at 30a. As a threshold matter, the court found, the district court had improperly shifted the burden to respondent "to show as a part of his initial claim that [petitioner]'s use was *not* experimental." *Id.* at 23a (emphasis added). But more fundamentally, the Federal Circuit held, the district court had operated under "an overly broad conception of the * * * experimental use defense." *Id.* at 24a.

The court of appeals explained that, under existing case law, the experimental use defense is "very narrow" and is confined to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Pet. App. 24a. According to the court, the defense does not insulate "conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications." *Id.* at 25a (citing *Pitcairn* v. *United States*, 547 F.2d 1106 (Ct. Cl. 1976), cert. denied, 434 U.S. 1051 (1978)). That general analysis, the court added, applies both to for-profit and nonprofit entities, including "major research universities," which "often sanction and fund research projects with arguably no commercial application whatsoever." *Ibid.*

The Federal Circuit emphasized that application of the experimental use defense requires "a[] detailed analysis of the character, nature and effect of the use." Pet. App. 25a. The district court in this case, the court found, "attached too great a weight to the non-profit, educational status of [petitioner]." *Id.* at 26a. Indeed, the court of appeals noted, petitioner, "like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." *Id.* at 26a n.7. The Federal Circuit thus remanded for reconsideration of petitioner's experimental use defense, stating that "[t]he correct focus should not be on the non-profit status of [petitioner] but on the legitimate business [petitioner] is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a.

DISCUSSION

The petition in this case should be denied. To date, the common law experimental use defense has been applied infrequently by the lower courts and only as a narrow exception to the general statutory prohibition on patent infringement. The Federal Circuit's treatment of that defense in this case is generally in line with the lower court case law that has developed in this area. While petitioner asserts that a more robust exception for experimental use is needed to accommodate university research in particular, the existing case law does not establish such an exception and any substantial altering of the balance between the goals of the patent laws and the demands of academic research calls for judgments that are legislative, not judicial, in nature.

Petitioner argues that the Federal Circuit's decision will render the experimental use defense unavailable to research institutions simply because their "legitimate business" *is* research. Pet. App. 25a. Although some language in the

opinion, in isolation, could support such an argument, that approach is not compelled by the decision when read as a whole. Under the Federal Circuit's decision, research institutions are neither automatically entitled to nor automatically ineligible for the experimental use defense. Thus, to determine whether the experimental use exception applies, the Federal Circuit instructed the district court on remand to consider not simply the legitimate business of petitioner, but the specific uses to which the patented inventions at issue were put. *Id.* at 26a. The record currently does not detail such uses, and that provides another reason to deny certiorari at this interlocutory stage of the case.

A. The Court Of Appeals' Decision Is Not Directly Contrary To Prior Case Law Applying The Experimental Use Defense

1. The Patent Act states that "whoever without authority * * * uses * * * any patented invention * * * during the term of the patent therefor, infringes the patent." 35 U.S.C. 271(a). The text of the Act does not expressly establish an experimental use exception. For some time, however, courts have recognized a limited experimental use exception to the statutory prohibition on the unauthorized use of a patented invention. The court of appeals' application of that judge-made defense in this case is generally in step with prior lower court precedent.

a. The common law experimental use defense traces its origins to an opinion by Justice Story in *Whittemore* v. *Cutter*, 29 F. Cas. 1120 (C.C. D. Mass. 1813). *Whittemore* was a patent case in which the defendant challenged the validity of a jury instruction. In the course of discussing that instruction, Justice Story observed that "it could never have been the intention of the legislature to punish a man, who constructed * * * a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining

the sufficiency of the machine to produce its described effects." *Id.* at 1121. That statement was dictum; the infringing activities at issue in *Whittemore* were not claimed to be experimental in nature and the defendant did not seek to avoid liability on that ground. But Justice Story's observation nonetheless provided the impetus for judicial recognition of an experimental use defense.

Since *Whittemore*, the experimental use defense has had a modest existence. The number of cases in which defendants have invoked the defense is relatively small; the number of times that courts have actually relied on it to excuse otherwise infringing conduct is smaller still; and this Court itself has not addressed the application of the defense. See Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 17-18 (2001) ("In practice, * * * the experimental use doctrine has rarely been applied in favor of an accused infringer.").[2]

b. The relatively minor role played by the experimental use defense is consistent with the limits placed on that defense by the text of the Patent Act and policies underlying that Act. The 1952 Patent Act by its terms prohibits any unauthorized "use" of a patented invention, 35 U.S.C. 154

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[2] Although this Court has not addressed the availability or scope of the experimental use defense to a claim of patent infringement, the Court has recognized a "distinction between inventions put to experimental use and products sold commercially," *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998), in the context of determining whether an invention was "in public use or on sale" more than one year before a patent application and thus ineligible for patent protection under 35 U.S.C. 102(b). See, *e.g.*, *Smith & Griggs Mfg. Co.* v. *Sprague*, 123 U.S. 249, 256 (1887). Although the Court's patentability cases do not discuss the exception at issue here, they nonetheless underscore that the determination whether an inventor has engaged in an experimental use may be highly fact specific. See *Root* v. *Third Ave. R.R.*, 146 U.S. 210, 221-226 (1892) (discussing experimental-use determinations in this context).

and 271(a), and does not contain any explicit exception for experimental uses. Cf. 35 U.S.C. 271(e) (exception for uses of certain patented inventions manufactured with DNA), discussed at pp. 16-17, *infra*. This Court has stated that "§ 271(a) of the [1952] Patent Code which defines 'infringement,' left intact the entire body of case law on direct infringement," *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 365 U.S. 336, 342 (1961), which would presumably include the judge-made experimental use defense. But even assuming that Congress intended to incorporate existing case law on that defense, Section 271(a)'s express prohibition of any unauthorized "use" of a patented invention precludes any role for an experimental use defense that goes beyond the traditionally narrow confines of the defense.

Similarly, the underlying premise of federal patent law, which is embodied in the Constitution itself, is that "the Progress of Science" is best promoted by giving inventors "the exclusive Right to their * * * Discoveries" during the limited term of a patent. U.S. Const. Art. I, § 8, Cl. 8. By vesting the patent holder with the right to exclude others from making, using, or selling the subject matter of his patent for a limited time, the patent laws provide a powerful incentive for scientific innovation and development. When the public is permitted to engage in the unlicenced use of patented inventions without incurring liability for infringement, even with respect to "experimental" uses that may offer other scientific benefits, the incentives provided by the patent laws are diminished and the nature of the patent "bargain" altered. *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). The more broadly that the experimental use defense is construed, the greater is the potential adverse impact on the patent bargain.

c. Courts have repeatedly emphasized that the experimental use defense is "narrow." See, *e.g.*, *Embrex, Inc.* v. *Service Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000)

(per curiam) (experimental use defense has been construed "very narrowly"); *Roche Prods., Inc.* v. *Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir.) ("truly narrow"), cert. denied, 469 U.S. 856 (1984); see also Mueller, *supra*, 76 Wash. L. Rev. at 17-18 (same). Typically, the defense is available only when an experiment is undertaken "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement." *Poppenhusen* v. *Falke*, 19 F. Cas. 1048, 1049 (C.C. S.D.N.Y. 1861). The defense ensures that individuals who experiment *on* a patented device simply to understand how it works will not face liability for patent infringement. Cf. *Whittemore*, 29 F. Cas. at 1121 (defense allows one to "ascertain[] the sufficiency of the machine to produce its described effects"). And thus in effect, the defense has excused only "de minimis" acts of technical infringement. *Embrex*, 216 F.3d at 1349; see *Roche*, 733 F.2d at 863 ("It is obvious here that it is a misnomer to call the [alleged experimental] use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned.").

2. a. Petitioner argues that the Federal Circuit's application of the experimental use defense in this case represents a significant break with prior case law applying the defense. Pet. 13-15. But the standards employed by the Federal Circuit below are drawn directly from prior decisions of the Federal Circuit and its predecessors. As noted, the court's observation that the experimental use defense is "very narrow and strictly limited" (Pet. App. 24a) has been repeatedly recognized by the case law. The principle that the defense is "limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" (Pet. App. 24a (internal quotation marks omitted)) was first announced as early as the 1860s and has been reiterated on several occasions since then. See *Poppenhusen*, 19 F. Cas. at 1049; *Roche*, 733 F.2d at 863; *Embrex*, 216 F.3d at 1349. And

the Federal Circuit's refusal to extend the defense to experimental uses that further a defendant's "legitimate business," even when that business is not commercial in nature (Pet. App. 26a), is drawn from *Pitcairn* v. *United States*, 547 F.2d 1106, 1125-1126 (Ct. Cl. 1976). See also *Douglas* v. *United States*, 181 U.S.P.Q. (BNA) 170, 177, aff'd on other grounds, 510 F.2d 364 (Ct. Cl. 1974), cert. denied, 423 U.S. 825 (1975).

b. Petitioner argues (Pet. 13) that the Federal Circuit's recitation of *Pitcairn*'s "legitimate business" language will strip academic institutions of the experimental use defense altogether, explaining that "[n]o research institution will be able to demonstrate that its experimental use of any patent fails to further the institution's 'legitimate business,'" "[b]ecause such entities are 'in the business' of research and education." Pet. 14. Although some language in the court of appeals' decision (see Pet. App. 25a) could support such an interpretation, that interpretation of the decision would produce the anomalous and untenable result of subjecting research institutions to a *disfavored* status under the experimental use defense. Moreover, read as whole, the court's decision is fairly susceptible of a much more routine and evenhanded application of the defense.

Indeed, in remanding the case, the Federal Circuit instructed the district court to focus on not only "the legitimate business [petitioner] is involved in," but also "whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Pet. App. 26a; see *ibid.* ("The correct focus should be * * * on the legitimate business [petitioner] is involved in *and* whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.") (emphasis added). If engaging in the "legitimate business" of research itself were enough to divest an institution of any experimental use defense, then there would have been no reason

for the court of appeals to have instructed the district court to undertake the second half of the inquiry set forth above.

The fact that the Federal Circuit remanded the case for further consideration of the availability of the experimental use defense and, in particular, the instructions that it gave concerning the "correct focus" (Pet. App. 26a) of the remand indicates that the decision is premised on a much more accommodating view of the application of the experimental use exception in the context of research institutions than the one feared by petitioner. The decision appears to premise the applicability of the experimental use exception on the specific actions of a research university, and not any wholesale determination that such institutions are categorically entitled to or ineligible for the defense. Moreover, at this interlocutory stage of the case, there is no reason to *assume* that the decision below will establish the sort of categorical and discriminatory rule against the application of the experimental use exception in the research-institution setting criticized by petitioner and its amici.

c. Petitioner asserts that, prior to the decision below, "case law [had] established that a research institution did not infringe a patent if it used a patented invention for experimental purposes only." Pet. 12. But the only case cited by petitioner for this "established" rule is a district court decision from 1935 that was reversed on appeal. See *Ruth* v. *Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 703 (D. Colo. 1935), rev'd on other grounds, 87 F.2d 35 (10th Cir. 1936). The United States is not aware of any other reported decision applying the experimental use defense to excuse otherwise infringing activities by a research institution. The present decision is the only one that has ever given extended consideration to how the defense should be applied in that context and the Federal Circuit's remand order leaves that issue open in this case. Accordingly, there is no direct conflict that warrants review by this Court concerning whether,

or when, research institutions in particular are entitled to the benefit of the experimental use exception.

d. At a more general level, petitioner asserts that the Federal Circuit's decision disregards the settled "dichotomy between commercial and non-commercial uses of a patent." Pet. 11. But that dichotomy is hardly clear-cut. During the past 20 years, there has been a growing trend toward the commercialization of academic research.[3] That trend has been accelerated by the enactment of federal laws, such as the Bayh-Dole Act, 35 U.S.C. 200 *et seq.*, that give universities broad latitude to take title to discoveries resulting from federally funded research and to grant exclusive licenses to private companies to commercialize those discoveries. It also reflects the growth of new industries with technological roots, such as biotechnology, software, and microelectronics; the increasing cost of conducting academic research; and federal policies that encourage collaborative university-corporate research activities. See Bok, *supra*, at 11-12; National Academy of Engineering, *supra*, at 98-99; Mueller, *supra*, 76 Wash. L. Rev. at 33-35; Michel, *supra*, 7 High Tech L.J. at 377-378. Thus, universities today are devoting increasing efforts toward the commercial exploitation of scientific research and the record suggests that petitioner itself has joined in that trend. See Pet. App. 26a n.7. There is nothing in the current patent laws to suggest that modern universities—many of which have themselves taken *advantage* of

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[3] See, *e.g.*, Derek Bok, *Universities in the Marketplace: The Commercialization of Higher Education* 57-78 (2003); Louis G. Tornatzky, et al., *Innovation U.: New University Roles in a Knowledge Economy* (2002) (case studies); Jennifer Croissant & Sal Restivo eds., *Degrees of Compromise: Industrial Interests and Academic Values* 55-100 (2001); National Academy of Engineering, *Technology Transfer Systems in the United States and Germany: Lessons and Perspectives* 91-123 (H. Norman Abramson, et al., eds. 1997); Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 71 High Tech. L.J. 367, 377-378 (1992).

patent protection and entered into licensing arrangements —are somehow outside the class of potential infringers because of an asserted non-commercial status.[4]

In any event, as noted above, in applying the experimental use defense, the Federal Circuit's decision in this case specifically calls for "a[] detailed analysis of the character, nature and effect of the [challenged] use." Pet. App. 25a. That kind of "detailed analysis," and not generalized assertions about the non-commercial or commercial character of academic research or major research universities, should guide the lower courts in this case in determining whether —in the light of a more fully developed factual record— petitioner's uses of respondent's patented inventions are a protected experimental use.

B. Petitioner's Broad Policy Concerns Are Speculative At This Time And Ultimately Are Better Suited For Legislative Rather Than Judicial Consideration

Petitioner argues that if research institutions are compelled by the Federal Circuit's decision to obtain licenses in order to use patented inventions for academic research, critical forms of scientific inquiry will be stunted. Pet. 16-25. But there is no reason to presume that the impact of the Federal Circuit's decision will be as severe as petitioner hypothesizes and, if problems materialize, Congress may be the proper forum to evaluate the problems and devise a comprehensive solution.

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[4] From 1979 to 1997, the number of patents awarded annually to universities increased nearly ten-fold, from 264 to 2,436. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289, 292 (2003). Today, universities earn more than one billion dollars per year in patent royalties and licensing fees. Bok, *supra*, at 12. Petitioner, "like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." Pet. App. 26a n.7.

1. Even assuming the Federal Circuit's decision substantially limits the availability of the experimental use defense, there are several reasons why the practical impact of that decision may not be as great as petitioner fears and why review is not warranted at this time to preempt any such potential impact. First, when academic scientists use patented inventions that are available for purchase, such as commercially available laboratory equipment or biological and chemical agents, they may be protected by the "first sale" doctrine. Under that doctrine, the sale of a patented invention by the patent holder carries with it an implied license for the purchaser to engage in the unrestricted use of the invention. See, *e.g.*, *Aro Mfg. Co.*, 377 U.S. at 484; *United States* v. *Univis Lens Co.*, 316 U.S. 241, 249-250 (1942); *Hewlett-Packard Co.* v. *Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1451-1452 (Fed. Cir. 1997), cert. denied, 523 U.S. 1022 (1998). As a result, when an academic researcher purchases a patented research tool, he is generally free to use it for experimental (or other) purposes.

Second, even in situations where the first-sale doctrine is not applicable, such as with respect to the use of patented processes or methods that are not subject to sale, it is unclear that the unavailability of the experimental use defense will be as disruptive to research efforts as petitioner asserts. Scientific research by America's pharmaceutical, chemical, and electronics industries has proceeded at a rapid and increasing pace even in the absence of the sort of experimental use defense that petitioner claims should be established for academic research institutions.

Third, petitioner's objections ultimately have less to do with the contours of the experimental use defense than with the underlying operation of the patent laws. The concerns identified by petitioner, such as the risk of exorbitant demands by patent holders, the transaction costs associated with obtaining licenses for "stacked" patents, and the un-

availability of inventions that are the subject of exclusive licenses, are not peculiar to the academic research environment; they are present whenever someone wishes to make use of a patented invention, regardless of the use to which the invention will be put. Those concerns inhere in Congress's underlying decision to grant patent holders an unqualified right "to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. 154(a)(1).

Fourth, petitioner's arguments ignore the practical consequences that could follow from giving academic research the kind of broad exemption from patent liability sought by petitioner. Recognition of a broad exemption from the patent laws for university research could have significant adverse effects on the incentive structure for inventions that have scientific and research applications. See, *e.g.*, Rai & Eisenberg, *supra*, 66 Law & Contemp. Probs. at 299; Michel, *supra*, 7 High Tech L.J. at 391-397. The problem may be particularly acute with respect to research tools, as to which researchers are "ordinary consumers." If academic researchers are categorically exempt from having to obtain licenses to use such tools, the financial impact on the patent holder may be severe and patent law incentives to innovate may be significantly diminished. See Rai & Eisenberg, *supra*, 66 Law & Contemp. Probs. at 299; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1035 (1989).

2. This is not to suggest that the academic and scientific community has not raised weighty concerns about the potential effect of the patent laws on academic research. However, any effort to develop a special rule to accommodate academic research within the framework of existing patent law would entail several different layers of policy judgments. For example, choosing the appropriate line between patent protection and the promotion of university research requires a series of judgments, including judgments concerning the

feasibility and cost of licensing arrangements among different types of research and different kinds of patents, the significance of differences in funding sources and commercial outcomes, the make-up of research institutions that might qualify for such assistance, and the respective incentives and disincentives of alternative liability rules.

Congress certainly has the capacity to balance those concerns and, if it perceives a sufficient problem with existing law, to fashion a comprehensive solution. But that would be a much more difficult and ungainly undertaking for the courts in devising or applying an experimental use defense. Indeed, it seems improbable that a 190-year-old, judge-made defense with little rooting in any statutory text could anticipate the challenges of the modern academic and research environment and adequately accommodate the competing policy concerns raised by the parties in this case.

Furthermore, Congress has demonstrated its sensitivity to the sort of policy concerns asserted by petitioner and its ability to address such concerns when it wants to. In *Roche*, the Federal Circuit held that the experimental use defense did not entitle a generic drug manufacturer to conduct experiments with a patented drug in order to prepare a new drug application under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* In response, Congress specifically amended the Patent Act to provide a narrowly tailored exception for the use of inventions "primarily manufactured using * * * site specific genetic manipulation techniques" when used "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. 271(e)(1).

Congress has subsequently entertained several proposals to enact additional exemptions for experimental uses, including one bill that would have established a general exemption for the use of patented inventions "for research or experi-

mentation purposes." See H.R. 5598, § 402, 101st Cong., 2d Sess. (1990) ("It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation"); H.R. 1556, § 2, 101st Cong., 1st Sess. (1989) (exemption for reproduction of transgenic farm animals); H.R. 4970, § 2, 100th Cong., 2d Sess. (1988) (exemption for making or use of genetically altered animals "solely for research or experimentation without any commercial intent or purpose"). To date, however, Congress has not enacted any of those proposed bills.

C. The Interlocutory Posture And Unusual Genesis Of This Case Also Counsel Against Granting Review

1. Even when an important threshold question has been decided by a court of appeals, this Court will "generally await final judgment in the lower courts before exercising [its] certiorari jurisdiction." *Virginia Military Inst.* v. *United States*, 508 U.S. 946 (1993) (Scalia, J., respecting the denial of certiorari). That customary practice is well-suited for the interlocutory petition in this case.

If this Court wishes to address the appropriate contours of the experimental use defense, it would benefit from doing so in the context of a fully developed factual record that clarifies precisely how the invention at issue was used by the alleged infringer. The summary judgment record in this case currently lacks such evidence, but the remand ordered by the Federal Circuit will give the parties an opportunity to present additional evidence on that critical factual issue. Regardless of how that evidence is evaluated by the lower courts of remand, its presence in the record would facilitate any subsequent deliberations by this Court on the proper scope of the experimental use exception.[5]

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[5] As discussed above, the Federal Circuit held that the district court had erroneously placed on *respondent* the burden of proving that peti-

2. Moreover, even if the evidentiary record were complete, this experimental use case arises in a somewhat unusual factual context. Infringement claims against university research programs are more likely to be asserted by commercial patent holders or competing research institutions, and when such claims are made, the experimental use defense is likely to have its greatest salience in connection with process and method patents. See *supra*, p. 14. Here, by contrast, the infringement claim against petitioner is being brought by a former employee; the dispute grows out of an employment dispute between respondent and petitioner; and the allegedly infringing activities involve the use of patented devices rather than patented processes or methods. The atypical factual setting of this case provides an additional reason for the Court to deny plenary review at this time and, instead, wait and see if more conventional patent infringement litigation develops in the research-university context in the wake of this case.

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tioner's use of his patented inventions was *not* solely experimental. See Pet. App. 22a-23a. Petitioner has not challenged that aspect of the court of appeals' decision in this Court. The fact that the district court applied an erroneous burden of proof itself may have affected the course of proceedings in the district court and contributed to the lack of factual development concerning the uses to which petitioner has put respondent's inventions. That in itself provides a significant reason to deny the petition and allow for the further proceedings called for by the Federal Circuit before considering whether this Court's review is warranted in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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No. 02-1007

IN THE

Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M. J. MADEY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONER

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INTRODUCTION

The United States never suggests that the Federal Circuit's decision is correct, nor, for that matter, does it even attempt to defend the Federal Circuit's rationale. Instead, it argues that the petition for certiorari should be denied for a series of wholly unsatisfactory reasons.

First, the United States contends that the decision "does not directly conflict with prior precedent" because the opinion relies on "legitimate business" language from a prior Federal Circuit decision.[1] The court of appeals took this prior, extraneous language completely out of context, however, and applied it in a manner that turns the experimental use exception on its head. Under the Federal Circuit's decision, research universities cannot invoke the experimental use exception because they are involved in educating and enlightening students and faculty. The determinative factor under prior precedent was the commercial nature of the allegedly infringing activity, not the educational status of the user.

Second, the United States suggests that "the procedural posture of this case will afford the lower courts with an opportunity on remand to clarify the scope of the experimental use defense after further factual development." U.S. Br. at 1. The Federal Circuit's decision, however, effectively forecloses Duke from mounting an experimental use defense on remand because, as the Federal Circuit unequivocally determined, Duke's legitimate business includes educating and enlightening its students and faculty. Contrary to the suggestion of the United States, moreover, further factual development is unnecessary under the appropriate standard. The summary judgment record is clear as to Duke's use of the patented FEL equipment, and shows that Duke has made no commercial use of the patents at issue in this case.

Third, the United States simply cannot explain away the importance of this case or its potentially devastating impact on

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1. Brief for the United States as Amicus Curiae ("U.S. Br."), at 1.

the university research community. *See* U.S. Br. at 14-15. The Federal Circuit's decision has upset a legal principle that has been relied upon by university researchers for decades: specifically, that non-commercial, basic scientific research falls within the experimental use exception. Unless the Court acts now to restore the experimental use exception to its proper bounds, university researchers will have to alter their ongoing research efforts immediately in response to the Federal Circuit's new standard.

Finally, the United States invites the Court to dodge the issue presented by this case because Duke's "policy concerns . . . may be better suited for legislative rather than judicial consideration." *Id.* at 1. Duke is not asking the Court to make a "policy" decision. It is asking the Court to declare what the law is, an act which, at least from the time of *Marbury v. Madison*, 5 U.S. 137 (1803), has been exclusively in the province of the judiciary. *See* 5 U.S. at 177. Only after the Court has spoken should Congress have reason to consider whether a policy change is in order.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION TURNED THE EXPERIMENTAL USE DOCTRINE ON ITS HEAD AND HAS FORECLOSED UNIVERSITY RESEARCHERS FROM RELYING ON THE DEFENSE.

The United States vainly attempts to rationalize the obvious conflict between the Federal Circuit's decision and prior case law. *See* U.S. Br. at 6-12. It cannot alter the simple fact, however, that the Federal Circuit conclusively decided that research universities may no longer rely on the experimental use exception to patent infringement liability – regardless of the specific nature of their activities – because it is their "legitimate business" to educate and enlighten. *See* App. at 25a.

The Federal Circuit overemphasized and misconstrued extraneous language from *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976), to create a new and unprecedented

experimental use test. In *Pitcairn*, the Court of Claims unremarkably concluded that testing of recently purchased aircraft by the United States is not covered under the common law experimental use exception to patent infringement liability. *See id.* at 1125-26. The result in that case cannot be questioned; the defendant had attempted to pass off its ordinary tests of new equipment as the type of "philosophical experiments" that satisfy the common law exception. The *Pitcairn* court succinctly disposed of the defendant's specious argument, stating: "Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency." *Id.*

The Federal Circuit seized upon the *Pitcairn* court's "legitimate business" language and applied it as though it were an independent requirement of the experimental use exception rather than simply language explaining why the tests at issue in *Pitcairn* were not the types of experiments covered by the exception. As a result, under the Federal Circuit's decision, to be entitled to the exception, a party must be engaged in "philosophical experiments" but it cannot be in the "business" of conducting "philosophical experiments." To satisfy the Federal Circuit's new test, an alleged infringer must show: (1) that its infringing acts were not "in furtherance of [its] legitimate business" ***and*** (2) that its infringing acts were "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." App. at 26a. On remand, unless Duke can satisfy ***both*** prongs of the new test, it will not be exempted from patent infringement. *See id.* ("So long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.").

In fact, the Federal Circuit already has decided that Duke ***cannot*** satisfy its new test because Duke fails under the first prong. The Federal Circuit unequivocally stated that the "legitimate business objectives" of a "major research university,"

including Duke, "include[es] educating and enlightening students and faculty . . . ." App. at 25a. Because any act by Duke in using the patented laser equipment will necessarily further its "business" of educating and enlightening its students and faculty, Duke essentially is foreclosed from relying on the experimental use exception on remand.

Significantly, the Federal Circuit's new standard is in direct conflict with a clear line of case law which, since 1813, has looked to the commercial versus non-commercial nature of the use, and not the status of the user, to determine whether the patent infringement exemption applies. *See, e.g.*, *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) ("[For] the making of a patented machine to be an offence within the purview of [the patent laws] must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."); *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11, 279) (considering it "well settled" that "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee"); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 703 (D. Colo. 1935) (explaining that use of patented parts "in laboratory machines used for experimental purposes" was not infringing use), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936); *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) ("We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."); *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (finding that defendant's tests were not immunized from patent infringement liability where the acts were performed "expressly for commercial purposes"). The Federal Circuit's departure from settled precedent has, indeed, produced an "anomalous and untenable result." U.S. Br. at 10.

II. THE FEDERAL CIRCUIT'S REMAND ORDER IS PURELY MINISTERIAL.

The Federal Circuit has already sealed Duke's fate in this matter. Although the Federal Circuit, consistent with the usual practice of appellate courts, remanded the case to the district court rather than entering summary judgment for the non-moving party, there is nothing for the district court to do on remand. The Federal Circuit explicitly found that Duke's "legitimate business" is educating and enlightening students. There is no need for the district court to examine the nature of Duke's actual research activities because Duke is foreclosed from relying on the experimental use exception under the first prong of the Federal Circuit's new experimental use standard.

The United States suggests that remand is necessary to allow for expansion of the record. *See* U.S. Br. at 17. The parties had a full opportunity to present evidence of Duke's use of the patented device, however, and Dr. Madey failed to present any evidence that Duke used it for commercial reasons. The Federal Circuit, moreover, did not state that the record required further development on the experimental use issue. *See* App. at 21a-26a. In fact, the record was complete enough for the Federal Circuit to make a *de novo* determination that "Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives." App. at 26a. Because the Federal Circuit's pronouncement on the scope of the experimental use defense is clear and final, the case is ready for this Court's review. *See Pharmaceutical Research & Mfrs. v. Walsh*, No. 01-188, slip op. at 14 (U.S. May 19, 2003) (plurality opinion); *cf. Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 180-81 (1988) (following the "'pragmatic approach' to questions of finality" for the purposes of granting certiorari) (citing *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 486 (1975)).

III. THIS CASE INVOLVES AN ISSUE OF PARAMOUNT NATIONAL IMPORTANCE.

The United States insists that the experimental use exception has played only a "minor role" through its "modest existence"

in case law. U.S. Br. at 7. The dearth of patent infringement suits against universities merely demonstrates that patent holders have recognized the traditional exception. The Federal Circuit's decision changes all that. The experimental use exception is anything but minor to research universities, which have relied on it to establish and maintain their research and educational programs. The United States did not, and cannot, refute that "[u]niversities will be forced to bear substantial administrative and financial costs to cover patent searches, infringement opinions, licensing agreements, and the inevitable litigation that will be engendered by the Federal Circuit's new rule of patent law."[2] Indirectly, the public at large will also suffer the negative repercussions of the Federal Circuit's decision.[3] This case is one of national importance, and warrants review by this Court. *Cf. Pharmaceutical Research*, No. 01-188, slip op. at 2 (describing a law that would "impose[] a significant burden on Medicaid recipients by requiring prior authorization in certain circumstances without serving any valid Medicaid purpose, and that . . . effectively regulates out-of-state commerce" by nonresident drug manufacturers as presenting questions "of national importance").

Similarly, the United States' attempt to downplay the potential impact of the Federal Circuit's decision on research universities cannot withstand scrutiny. *See* U.S. Br. at 14-15. First, the United States suggests that the "first sale" doctrine will still protect research universities from patent infringement claims for their use of commercially purchased laboratory equipment and biological and chemical agents. *See id.* at 14. The first sale doctrine, however, will hardly fill the void left by the Federal Circuit's disruption of the experimental use

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2. Brief for Association of American Medical Colleges, *et al.*, as *Amici Curiae* in Support of Petitioner, at 3.

3. *See generally* Brief of *Amici Curiae* Consumer Project on Technology and Public Knowledge in Support of Petition for Writ of *Certiorari*, at 7-8.

exception.[4] Specifically, its application is limited to the sale of tangible patented items. *See generally United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942) ("Our decisions have uniformly recognized that the purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward for the use of his invention by sale of the article . . . ."). Basic scientific research at universities, however, is dependent on patented methods and processes, not just patented equipment.

Second, the United States suggests that, because industrial researchers have been able to function without the benefit of the experimental use exception, university researchers can similarly adapt and flourish. *See* U.S. Br. at 14. The United States, however, cites no evidence that industrial concerns, unlike research universities, have relied on the experimental use exception. Furthermore, although the economic incentives of industrial research may justify the significant up-front expenditures needed to work through the patent "due diligence" and licensing process, the same may not be true for basic scientific research. There is no certainty, therefore, that basic scientific research will be able to continue on a consistent course if the Federal Circuit's opinion is allowed to stand.

Third, the United States contends that the restrictions of the patent monopoly are, in essence, a necessary evil of the patent laws, to which university researchers have no choice but to submit. *See id.* at 14-15. The United States argues that the

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4. Moreover, as this case has shown, even universities that hold clear title to patented equipment are not immune from allegations of infringement. The Department of Defense, in an exhaustive property audit conducted through the auspices of the Office of Naval Research ("ONR"), has concluded that Duke owns the Mark III FEL. The ONR's property report, which is part of the record in this case, conclusively rebuts the suggestion by the United States that the Department of Energy owns this equipment. *See* U.S. Br. at 2 n.1. Despite the fact that Duke holds title to the Mark III, Dr. Madey still asserts that the university does not have a right to practice the patented technology embodied in the laser equipment.

restrictions of the patent laws are common to all who seek to use patented devices and research tools, "regardless of the use to which the invention will be put." *Id.* at 15. The experimental use exception, when properly construed and applied, flatly contradicts this statement. A person or entity that uses a patented invention for "philosophical experiment or to ascertain the verity and exactness of the specification," is not restricted by the patent monopoly, and may practice the patent for those limited purposes. *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391). The United States also appears to be overly solicitous of the interests of the patentee. It recognizes that a patent "bargain" is inherent in the Constitution, but then isolates the need to protect the patent monopoly as the sole means of achieving that balance. *See* U.S. Br. at 8. The patent bargain, however, is just that – a bargain; the inventor's monopoly is not absolute. *See United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) ("[T]he promotion of progress and science and the useful arts is the 'main object' [of the patent system]; reward of inventors is secondary and merely a means to that end.") (citing *Pennock v. Dialogue*, 2 Pet. 1, 19 (1829)).

Finally, the United States erroneously argues that Duke is seeking to expand the common law experimental use exception to broadly cover all university research activities. *See* U.S. Br. at 5, 15. This is not the case. Instead, Duke simply wants the benefit of the same patent infringement exception that is available to non-educational research entities. Duke, therefore, is requesting that the Court review this case and clarify that educational research institutions are not ***foreclosed*** from relying on the experimental use exception simply because they are "in the business" of education and enlightenment. Otherwise, the Federal Circuit's decision promises immediate, detrimental effects on university research nationwide.

IV. THE COURT, NOT CONGRESS, SHOULD DECIDE THIS ISSUE.

Duke is not seeking review by the Court to elicit "a more robust" experimental use exception. *See* U.S. Br. at 5. It is,

however, seeking clarification of the proper scope of the exception and reasoned guidance as to how this long-standing common law doctrine applies to its free electron laser research activities. The United States' pessimistic view "that a 190-year-old, judge made defense with little rooting in any statutory text could [not] anticipate the challenges of the modern academic and research environment and adequately accommodate the competing policy concerns raised by the parties in this case," U.S. Br. at 16, ignores the prominent role of courts in interpreting, applying, and developing intellectual property law. *See, e.g., Roche Prods., Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 861 (Fed. Cir. 1984) ("Because Congress has never defined use, its meaning has become a matter of judicial interpretation."); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 26 (1997) (explaining the judicially created doctrine of equivalents).[5] It is now time for the Court to delineate the proper contours of the experimental use defense to cases of university research.[6] *See Marbury v. Madison*, 5 U.S. 137, 177

5. *See generally* Pierre N. Leval, *Toward a Fair Use Standard*, 103 Harv. L. Rev. 1105 (1990) (discussing the judicially created fair use exception to copyright infringement). The fair use doctrine, which is analogous to the experimental use exception, is a telling example of the critical role of courts in developing this area of intellectual property law. Although the fair use doctrine, whose genesis also is traced to Justice Story, was eventually codified in 1976, Congress still "intended that courts continue the common-law tradition of fair use adjudication." *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 577 (1994) (citations omitted). This reflects the fact that determining fair use, much like experimental use, "calls for case-by-case analysis." *Id.* (citations omitted). The United States, therefore, is misguided if it believes that Congress will be in the best position to address, in one legislative act, all the potential issues that may arise under the experimental use exception.

6. The United States points out that Congress has not yet codified the experimental use exception. *See* U.S. Br. at 16-17. If such inaction is persuasive on any point, it should be read to imply congressional acquiescence in and agreement with existing case law. *Cf. Warner-*

(Cont'd)

(1803) ("It is emphatically the province and duty of the judicial department to say what the law is. Those who apply the rule to particular cases, must of necessity expound and interpret that rule.").

CONCLUSION

The Court should grant the petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit.

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(Cont'd)

Jenkinson, 520 U.S. at 28 ("Congress can legislate the doctrine of equivalents out of existence at any time it chooses."). Indeed, the absence of congressional action on this issue can be attributed, at least in part, to Congress's reliance on the stability of the common law experimental use doctrine. *See* H. Rep. 101-960, Part 1 (1990) (explaining that a statutory provision to include an experimental use exemption to the transgenic animal patent bill (H.R. 4970) had been deleted because ***"an exemption already existed in the patent case law"***) (emphasis added).

(3)

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Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF FOR ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether universities are precluded from asserting the federal common law experimental use exemption from liability for patent infringement merely because their scientific research programs serve legitimate educational purposes.*

* The thiry-one *amici curiae* are listed in the Appendix, *infra.*

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M. Thayer & R. De Liberty, "The Research Exemption to Patent Infringement: The Time Has Come for Legislation," 4 J. Biolaw & Bus. 1 (2000) 11

J. Walsh, A. Arora, and W. Cohen, "The Patenting and Licensing of Research Tools and Biomedical Innovation," in National Academy of Sciences, *Patents in the Knowledge-Based Economy* (2003) 8

IN THE

Supreme Court of the United States

No. 02-1007

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M.J. MADEY

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICI CURIAE* [1]

Amici curiae represent universities whose faculties engage in scientific research. They consist of the **Association of American Medical Colleges,** whose membership includes 125 medical schools, nearly 400 teaching hospitals and health systems, and 92 academic societies with an aggregate indi-

[1] The following representations are made pursuant to Sup. Ct. R. 37: The parties have consented to the filing of this brief; no counsel for either party authored any portion of this brief; no persons other than *amici curiae* made any monetary contribution to the preparation or submission of this brief.

vidual membership of approximately 100,000; the **American Council on Education,** representing approximately 1800 colleges and universities and serving as a forum for consideration of higher education issues of national importance; the **Association of American Universities**, whose 62 members include most of the nation's leading public and private research universities; the **National Association of State Universities and Land Grant Colleges**, representing public universities from all 50 states; the **Council on Governmental Relations**, an association of 150 research-intensive universities devoted to maximizing the scientific benefit from federal investment in academic research; the **Association of University Technology Managers**, a non-profit organization of approximately 3300 professionals dedicated to issues related to technology transfer; **Public Citizen, Inc.**, a public interest advocacy group; the **Howard Hughes Medical Institute**, which supports research conducted by faculty with joint appointments at universities and the Institute; and the following individual colleges, universities, and medical schools: **Baylor College of Medicine; The Regents of the University of California; Carnegie Mellon University; Emory University; University of Florida; Georgetown University; The George Washington University; Iowa State University of Science and Technology; Johns Hopkins University; University of Kentucky; University of Maryland; Massachusetts Institute of Technology; Mount Sinai School of Medicine; New York University; The University of North Carolina at Chapel Hill; University of Pittsburgh; Rutgers, the State University of New Jersey; University of Texas at Austin; Texas A&M University; Vanderbilt University; University of Washington; Washington State University; and Yale University.**

Universities spent more than $30 billion on scientific research and development in calendar year 2000. National Science Foundation, *Science and Engineering Indicators*

2002, App. Table 5-2 (2002). The *amici curiae* all directly engage in or actively support such university-based scientific research. The decision by the Federal Circuit in this case, however, poses a serious threat not only to the viability of many individual academic research projects but also to the vitality of academic scientific research generally. The *amici curiae* have an obvious and very strong interest in this case and in the reversal of the decision below.

INTRODUCTION

The Federal Circuit's decision limiting the scope of the common law experimental use exemption from liability for patent infringement is of immense importance to all universities whose faculties engage in scientific research. By effectively eliminating the exemption for even noncommercial academic scientific research, the decision erects a significant roadblock to the advancement of science. The *amici curiae* are deeply disturbed by this ruling. *See* Note, "Universities Ask Supreme Court to Reverse Patent Ruling," 299 Science 26 (January 3, 2003). In the past, university-based research has been crucial to scientific progress on almost every front. The decision below threatens to stifle that research and thereby endanger this nation's continued leadership in science and technology. The question presented by this case is vital to the nation's scientific wellbeing.

Universities will be forced to bear substantial administrative and financial costs to cover patent searches, infringement opinions, licensing agreements, and the inevitable litigation that will be engendered by the Federal Circuit's new rule of patent law. The money diverted into such uses will no longer be available for actual research. As a result of these additional costs and also the associated delays occasioned by patent searches and the negotiation of licenses, university-based research programs will be curtailed and research projects abandoned. In many situations patent holders are likely to use the court's ruling as a basis for imposing onerous

financial or nonfinancial licensing terms or even as a means of barring entire lines of what they may view as potentially competing scientific research. These developments place in jeopardy the research plans and activities of thousands of science graduate students and faculty researchers.

There is a serious risk that the Federal Circuit's decision will significantly impede this nation's scientific progress. In the end, the burden will be borne by the general public in its capacity as consumer and beneficiary of the scientific advances the patent system is intended to foster. The *amici curiae* ask this Court to grant review and reverse in order to avert the drastic consequences that otherwise can be expected to flow from the decision below.

SUMMARY OF ARGUMENT

The experimental use exemption historically has protected noncommercial research from claims of patent infringement; although prior to this case there had been virtually no litigation with respect to academic scientific research *per se*, the scientific community had every reason to believe that the exemption would protect noncommercial academic research just as it protected other noncommercial research.

The decision below radically departs from prior law. Without inquiring into the commercial or noncommercial nature of the research at issue, the Federal Circuit announced that universities are ineligible to claim the experimental use exemption for the paradoxical reason that the scientific research in which they are engaged serves legitimate educational purposes. The obvious result of this ruling is to deny the experimental use exemption with respect to all scientific research conducted at universities and other nonprofit research institutions, even when that research is manifestly noncommercial.

The Federal Circuit's holding in this case will have a significant chilling effect on all academic scientific research,

and especially that in biotechnology and biomedicine. Depriving university scientists of the experimental use exemption will directly and significantly increase the cost of basic research, the great majority of which is supported by competitively awarded federal funds. In many situations, the unanticipated need to negotiate licenses before initiating or while in the midst of research projects may forestall or seriously disrupt ongoing research. In some circumstances, patent holders may refuse licenses and thus bar research from going forward at all. The *amici curiae* are gravely concerned that, if the experimental use exemption is no longer available, the proliferation of patents on upstream tools for biotechnological, biomedical, and advanced electronic research will have a very adverse effect on basic and applied downstream research activity at universities and other nonprofit research institutions.

This Court should grant review to restore the federal common law experimental use exemption to its traditional role as a safe haven for noncommercial scientific inquiry.

ARGUMENT

A. The Experimental Use Exemption Historically Has Protected Noncommercial Research From Claims Of Patent Infringement

"[T]he courts have long recognized . . . that a purely 'experimental use' of a patented invention, with no commercial purpose, should be exempt from infringement liability." R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 U. Chi. L. Rev. 1017, 1018-19 (1989). This experimental use exemption, which was first articulated by Justice Story in *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813), serves a purpose somewhat analogous to that of the fair use doctrine of copyright law. J. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement

for Biomedical Research Tools," 76 Wash. L. Rev. 1, 42-43 (2001); M. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law," 100 Colum. L. Rev. 1177, 1192-94 (2000). The exemption ultimately is grounded in the same constitutional rationale as the patent system itself: scholarly freedom to use and build upon patented advances in the course of noncommercial scientific inquiry is of critical importance to "the Progress of Science and useful Arts." U.S. Const., Art 1, Sec. 8. *See* I. Feit, "Biotechnology Research and the Experimental Use Exception to Patent Infringement," 71 J. Pat. & Trademark Off. Soc'y 819, 839 (1989).

In determining the type of "experimental use" entitled to exemption, courts historically drew the line between commercial and noncommercial research. Noncommercial research was protected. For example, the exemption covered the federal government's use of a patented alloy "for experimental purposes." *Chesterfield v. United States,* 159 F. Supp. 371, 375 (Ct. Cl. 1958). In the only reported case involving an academic institution (the Colorado School of Mines) the court explained that the "making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement." *Ruth v. Stearns-Roger Mfg. Co.,* 13 F. Supp. 697, 713 (D. Colo. 1935), *rev'd on other grounds,* 87 F.2d 35 (10th Cir. 1936).

In contrast, commercial research was not protected. A major landmark in this regard was *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 1984), where the Federal Circuit held that the experimental use exemption does not cover one pharmaceutical company's use of another's patented drug for the purpose of performing tests necessary to obtain regulatory approval of its own competing version of the drug. The court explained, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,'

when that inquiry has definite, cognizable, and not insubstantial commercial purposes." *Id.* at 863. *See also Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (holding, in a patent dispute between two commercial competitors, that the experimental use exemption does not protect research performed "expressly for commercial purposes").

"[A]fter *Roche,* scientists engaged in research and development having more than negligible commercial purpose could no longer rely on the experimental use doctrine." J. Mueller, *supra*, 76 Wash. L. Rev. at 24. Yet with its emphasis on the distinction between commercial and noncommercial purposes, *Roche* appeared to confirm that genuinely noncommercial scientific research undertaken by university scientists or government researchers remained protected by the experimental use exemption. As one writer put it shortly after *Roche*, "[f]ew would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function." R. Hantman, "Experimental Use as an Exception to Patent Infringement," 67 J. Pat. & Trademark Off. Soc'y 617, 633 (1985).

Subsequent developments provided further support for the view that traditional noncommercial scientific research falls well within the protective scope of the experimental use exemption. Congress, believing that *Roche* had improperly narrowed the exemption, enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 271(e), reversing the result in that case and thereby extending protection even to certain specified commercial research activities. The Federal Circuit seemingly took this to heart, giving the new statute a broad reading in *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405-06 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

This history afforded university communities and patent holders alike strong reason to believe that Justice Story's experimental use exemption continued to protect noncommercial academic research from claims of patent infringement. A recent study, based upon "70 interviews with personnel at biotechnology and pharmaceutical firms and universities," confirms that "university researchers, to the extent that they are doing noncommercial work, are largely left alone" and that in those rare instances when universities received letters alleging infringement "the typical response was effectively to ignore such letters and inform the [patent] holder that the university was engaged in research, did not intend to threaten the firm's commercial interests, and would not cease its research." J. Walsh, A. Arora, and W. Cohen, "The Patenting and Licensing of Research Tools and Biomedical Innovation," 2, 35, in National Academy of Sciences, *Patents in the Knowledge-Based Economy* (2003).

B. The Decision Of The Federal Circuit In This Case Radically Departs From Prior Law By Denying The Experimental Use Exemption To All Academic Scientific Research, Even When That Research Is Manifestly Noncommercial

The Federal Circuit in this case eschewed any inquiry into whether the research at issue was genuinely noncommercial. Instead, the court issued a broad ruling effectively denying the experimental use exemption to all university-based research in all circumstances.

In an opinion frankly hostile to the experimental use exemption, the Federal Circuit essentially disavowed prior law with its clearly drawn distinction between commercial and noncommercial research. The court held, instead, that the exemption is not available to nonprofit universities *because scientific research at those universities serves legitimate educational purposes*:

> [M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. . . .
>
> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

This decision is both bad law and bad policy. The distinction between commercial and noncommercial research always has been the touchstone of the experimental use exemption. Indeed, when he first articulated the doctrine in *Whittemore* Justice Story was specifically contrasting "philosophical experiments" with "use [of the patented invention] for profit." 29 F. Cas. at 1121. Scientific research directed toward "educating and enlightening students and faculty," *Madey*, 307 F.3d at 1362, is exactly the sort of activity embraced by the early nineteenth-century expression "philosophical experiments." L. Bruzzone, "The Research Exemption: A Proposal," 21 AIPLA Q. J. 52, 60 (1993).

Noncommercial academic scientific research logically lies at the very core of the experimental use exemption. R. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 97 Yale L.J. 177, 223 (1987). Yet the Federal Circuit appears now to have made the exemption inapplicable to virtually all truly serious scientific research. This creates a substantial likelihood that "the patent system

[will] function to thwart the very innovation that it is intended to foster." M. O'Rourke, *supra*, 100 Colum. L. Rev. at 1180.

The Federal Circuit was led astray by language in *Pitcairn v. United States,* 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978), holding that the experimental use exemption did not apply when the government was merely engaged in testing newly purchased helicopters to make sure that they worked properly. There can be no quarrel with the result in *Pitcairn*: routine testing of equipment is not truly scientific research and need not be protected as "experimental use." In justifying that unexceptionable result, however, the *Pitcairn* court explained, somewhat infelicitously, only that the government's use of the helicopters had been "in keeping with the legitimate business of the using agency." *Id.* at 1125-26.

The expression "legitimate business" was seized upon by the Federal Circuit in this case without paying due attention to context. The *Pitcairn* court had employed that expression offhandedly, as a way of indicating that the government was not actually engaged in scientific research but rather was simply ascertaining, before placing its helicopters in regular use, that they were capable of being operated in the manner intended. The Federal Circuit here misread *Pitcairn,* making the inquiry focus on the relationship of the patented invention's use to the defendant's "business" rather than on whether that use genuinely constitutes noncommercial scientific research. The court lost sight of the values furthered by the experimental use exemption and, in doing so, constructed an apparently absolute barrier to a claim of exemption by any modern research university (or by any government agency or other nonprofit organization, for that matter) engaged in the "business" of noncommercial scientific research.

C. The Decision Below Will Have A Significant Chilling Effect On Academic Scientific Research, Especially In Biotechnology And Biomedicine

"[A] significant portion of scientific innovation occurs in university, government, and private non-profit environments . . . ." E. Barash, "Experimental Uses, Patents, and Scientific Progress," 91 Nw. U. L. Rev. 667, 696 (1997). Much of this scientific innovation results from basic research that is directed toward the general acquisition and dissemination of scientific knowledge and has no explicit commercial objective.

Universities and university scientists—to the extent they consider the issue at all—assume that their noncommercial research is exempt. *See* M. Thayer & R. De Liberty, "The Research Exemption to Patent Infringement: The Time Has Come for Legislation," 4 J. Biolaw & Bus. 1, 2 (2000). They "rarely check the patent literature to determine whether their proposed research will infringe on any patents." E. Barash, *supra*, 91 Nw. U. L. Rev. at 698. Nor are they in a position to do so. "While corporations have legal departments geared towards answering potential legal quagmires, universities do not have the infrastructure to render routine opinion work to researchers." *Id.* Universities are "ill equipped to handle multiple transactions for acquiring licenses to use research tools." M. Heller & R. Eisenberg, "Can Patents Deter Invention? The Anticommons in Biomedical Research," 280 Science 698, 700 (1998).

The decision below works a drastic change in the legal environment. Depriving university scientists of the experimental use exemption will directly and significantly increase the cost of basic research even when patent holders are willing to make licenses available:

> [L]icensing patented inventions used in basic research poses special problems. The need to obtain licenses would add significant administrative and financial bur-

> dens to researchers in fields where patent protection is widespread. Most research builds on prior discoveries. If a significant number of these are patented, obtaining licenses on each would generate mounting royalty and transaction costs.

S. Michel, "The Experimental Use Exception to Infringement Applied to Federally Funded Inventions," 7 High Tech. L. J. 369, 398 (1992). The need to allocate scarce university resources to the processing of scientifically unproductive administrative and legal paperwork will involve a significant diversion of funds away from educationally more important activities, including actual scientific research.

There will be not only greater costs but longer delays in getting research started if, indeed, patent holders permit it to be undertaken at all. The need to obtain licenses will constitute an initial and major hurdle in the path of many projects. "Delays in negotiating multiple agreements to use patented processes, reagents, and gene fragments could stifle the creative give-and-take of academic research." M. Heller & R. Eisenberg, *supra*, 280 Science at 700.

The added cost of conducting patent searches and paying for licenses, and the concomitant delays in launching research projects, are not the only, and may not be the worst, problems facing universities and their researchers in the wake of the decision below. The unanticipated need to acquire licenses in the midst of a project can seriously disrupt if not entirely derail ongoing research. It simply "is not practical for researchers to wait for a patent infringement evaluation each time they perform a basic laboratory technique." I. Feit, *supra*, 71 J. Pat. & Trademark Off. Soc'y at 822. Research does not follow in a straight line. One line of inquiry will often open up an entirely new line of inquiry not contemplated at the outset. To halt research in mid-stream for months or years in the face of an unanticipated need to obtain a license—or even worse, to be required to abandon the

research altogether upon the denial of a license—will have a very serious deleterious effect on the competitive advantage American universities' research programs currently have in the world. *See* R. Eisenberg, *supra*, 56 U. Chi. L. Rev. at 1056.

In some circumstances, the absence of an experimental use exemption may make it altogether impossible to undertake a planned research project. As the National Institutes of Health has observed, "[p]rogess in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout the government, academia, and industry." 64 Fed. Reg. 72090, 72093 (1999). It follows that "intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research . . . ." *Id.* at 72092. The problem is that "some patent holders will undoubtedly object to the use of their inventions in subsequent research and, in the absence of an experimental use exemption, might use their exclusive rights to stop valuable research from proceeding." R. Eisenberg, *supra*, 56 U. Chi. L. Rev. at 1072. This "could undermine a critical mechanism of the scientific community for facilitating the progress of science." R. Eisenberg, *supra*, 97 Yale L.J. at 225.

Even before the decision below, many commentators were concerned that the Federal Circuit's emphasis in *Roche* on the narrowness of the experimental use exemption "could have significant chilling effects on research efforts." L. Bruzzone, *supra*, 21 AIPLA Q. J. at 65; *see also, e.g.*, S. Michel, *supra*, 7 High Tech. L.J. at 389-90; E. Barash, *supra*, 91 Nw. U. L. Rev. at 698. By effectively abolishing the experimental use exemption for all academic scientific research, the decision below magnifies the problem enormously. The Federal Circuit's opinion in this case will have a very damaging chilling effect on all university-based scientific research.

This chilling effect will be felt in all scientific areas where patent protection has been granted to intellectual advances that may form part of the foundation for further research, including chemistry, physics, and advanced electronics. The problem may be at its most severe, however, in biotechnology and biomedicine:

> The explosion of biotechnological and biomedical research and development in the United States in the past twenty years, with a corresponding increase in patenting activity, particularly in the area of genomics, has concomitantly heightened difficulties of access to and dissemination of patented research tools. Burgeoning research and development will require ever-greater numbers of proprietary tools, giving rise to transaction costs associated with acquiring the right to use each tool. In some cases, the patentee may refuse to license the research tool altogether.

J. Mueller, *supra*, 76 Wash. L. Rev. at 5-7. The *amici curiae* are gravely concerned that the decision below will encourage patent holders to assert claims in a manner that will impede or altogether frustrate university scientists' ability to make further basic advances in critical areas of biotechnology and biomedicine.

The past two decades have seen "a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research." M. Heller & R. Eisenberg, *supra*, 280 Science at 698. "Patented research tools" now include such things as "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools." 64 Fed. Reg., *supra*, at 72092 n.1. For example, "[m]any of the pioneering developments in basic laboratory methods necessary for recombinant DNA experiments have been patented." I. Feit, *supra*, 71 J. Pat. & Trademark Off. Soc'y at 820.

Many patents in the field of biotechnology do not cover products or even methods but are essentially informational in nature, covering such matters as anonymous gene fragments and protein crystalline coordinates. *See, e.g.*, M. Heller & R. Eisenberg, *supra*, 280 Science at 699. For example, patents have been granted on the identification of "small segments of complimentary DNA [that] have no presently known utility [but] are believed to be useful as probes in searching for corresponding full-length genes." J. Mueller, *supra*, 76 Wash. L. Rev. at 13-14. The inability to work with such information could blunt the promise of the remarkable achievement of the Human Genome Project by crippling follow-on basic research in fields such as genomics and proteomics (the study of proteins and their functions within the cell) and significantly impair academic researchers' ability to achieve important new breakthroughs in biomedical science.

The magnitude of the problem is suggested by recent action taken by Hoffman-La Roche Corporation ("Roche") with respect to its patents over the thermostable enzyme Thermus aquaticus YTl DNA polymerase ("Taq") and polymerase chain reaction ("PCR"). Taq is a basic biotechnology tool "widely used in DNA sequencing." J. Mueller, *supra*, 76 Wash. L. Rev. at 2. PCR is "the revolutionary DNA amplification process that utilizes Taq." *Id.* at 3. In 1995,

> Roche accused more than forty U.S. universities and research institutes (including Harvard, Stanford, Massachusetts Institute of Technology, the Salk Institute, the Scripps Research Institute, and the National Cancer Institute) and more than 200 individual scientists of infringing these patents. . . . Roche officials professed no concern about the use of Taq for 'pure research' purposes, but stated that they felt compelled to take

> action against those scientists engaged in what Roche termed 'highly practical' research with potential profit-making potential.

Id. Roche and other similarly situated patentees may be emboldened by the decision below to extend their aggressive patent enforcement to noncommercial "pure research" as well. *See id.* ("a Roche spokesperson . . . warned that she 'wouldn't want to predict what action Roche would take relative to any patent . . . in the future'"). This poses a major threat to the continued vitality of noncommercial academic biotechnological and biomedical research programs.

This nation has benefited enormously in the past from noncommercial academic scientific research, as more discoveries and greater understanding of the unknown have pointed toward and facilitated commercial research leading to new and socially beneficial products and applications. The Federal Circuit's decision threatens to retard this process significantly. Even before the decision below, there was grave concern in the scientific and public policy communities that "the proliferation of patents on 'upstream' basic tools of biotechnological and biomedical research will stymie the development of . . . downstream application[s]." J. Mueller, *supra*, 76 Wash. L. Rev. at 7. The denial of experimental use protection for noncommercial academic scientific research will make a difficult situation much worse.

D. This Court Should Grant Review To Restore The Federal Common Law Experimental Use Exemption To Its Traditional Role As A Safe Haven For Noncommercial Scientific Inquiry

This Court should grant the petition for certiorari and hold that universities are not precluded from asserting the experimental use exemption merely because their research programs serve legitimate educational purposes.

The issue clearly is important. Respondent may argue, however, that certiorari should be denied because there is no conflict among the circuits and the matter is interlocutory. In the circumstances of this case, those factors do not genuinely militate against review.

The Federal Circuit has exclusive appellate jurisdiction over cases arising under federal patent law. 28 U.S.C. § 1295(a)(1). Thus there is and will be no conflict among the circuits on the reach of the experimental use exemption. But this does not mean that this Court should defer to the Federal Circuit's presumed expertise and leave standing the harmful and misguided ruling below. As Justice Stevens recently noted, "decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias." *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 122 S.Ct. 1889, 1898 (2002) (concurring). This case presents an issue of federal common law that is too important to be left to a specialized patent court; this Court, with its broader perspective, should intervene to resolve the issue.

Although the case nominally is interlocutory, there is nothing further to be done on remand with respect to the experimental use exemption. The Federal Circuit has noted that Duke University's scientific research projects "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty" and has held that any act "in furtherance of the alleged infringer's legitimate business . . . does not qualify for the very narrow and strictly limited experimental use defense." *Madey*, 307 F.3d at 1362. As a practical matter, that forecloses Duke from asserting the experimental use defense on remand. Moreover, even if on remand Duke were to prevail on other grounds, the Federal Circuit's ruling with respect to experimental use still would stand as the radically new and disruptive law of the land.

As long as it does remain standing, the Federal Circuit's ruling will raise serious concerns and cause serious harm to American universities, to the academic scientific research community, and to "the Progress of Science and useful Arts." U.S. Const., Art 1, Sec. 8. The case warrants immediate plenary review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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January 2003

APPENDIX

LIST OF *AMICI CURIAE*

The foregoing brief is filed on behalf of the following organizations as *amici curiae*:

American Council on Education
Association of American Medical Colleges
Association of American Universities
Association of University Technology Managers
Baylor College of Medicine
Carnegie Mellon University
Council on Governmental Relations
Emory University
Georgetown University
Howard Hughes Medical Institute
Iowa State University of Science and Technology
Johns Hopkins University
Massachusetts Institute of Technology
Mount Sinai School of Medicine
National Association of State Universities and Land Grant Colleges
New York University
Public Citizen, Inc.
Rutgers, the State University of New Jersey
Texas A&M University
The George Washington University
The Regents of the University of California
The University of North Carolina at Chapel Hill
University of Florida
University of Kentucky
University of Maryland
University of Pittsburgh
University of Texas at Austin
University of Washington
Vanderbilt University
Washington State University
Yale University